UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to_____

Commission file number 001-14053

Milestone Scientific Inc.
(Exact name of registrant as specified in its charter)

Delaware	**13-3545623**
State or other jurisdiction of Incorporation or organization	**(I.R.S. Employer Identification No.)**

425 Eagle Rock Avenue, Roseland, NJ 07068
(Address of principal executive offices)
Registrant's telephone number, including area code: 973-535-2717

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Symbol	Name of each exchange on which registered
Common Stock, par value $.001 per share	MLSS	NYSE American

Securities registered pursuant to section 12(g) of the Act: **NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☑ No
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☑ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☑ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☑ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment of this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☑
Emerging Growth Company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

As of June 28, 2019, the last business day of the registrants most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the issuer was $15,368,647. This amount is based on the closing price of $.36 per share of the registrant's common stock as of such date, as reported on the NYSE American. As of March 30, 2020, the registrant has a total of 49,893,534 shares of Common Stock, par value $0.001 per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

MILESTONE SCIENTIFIC INC.
Form 10-K Annual Report
TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K are "forward-looking statements" (within the meaning of the Private Securities Litigation Reform Act of 1995) regarding the plans and objectives of management for future operations. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Milestone Scientific Inc. ("Milestone Scientific") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Milestone Scientific's plans and objectives are based, in part, on assumptions involving the continued expansion of its business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific. Although Milestone Scientific believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. Considering the significant uncertainties inherent in the forward-looking statements included herein, particularly in view of our history of operating losses that are expected to continue, requiring additional funding which we may be unable to raise capital when needed (which may force us to delay, curtail or eliminate commercialization efforts of our CompuFlo Epidural Computer Controlled Anesthesia System), the early stage operations of and relatively lack of acceptance of our medical products, relying exclusively on two third parties to manufacture our products, changes in our informal manufacturing arrangements made by the manufacturer of our products and disruptions at the manufacturing facility of our manufacturers exposes us to risks that may harm our business, raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights, if physicians do not accept nor use our CompuFlo Epidural Computer Controlled Anesthesia System, our ability to generate revenue from sales will be materially impaired, exposure to the risks inherent in international sales and operations, including China, and developments by competitors may render our products or technologies obsolete or non-competitive, the inclusion of such information should not be regarded as a representation by Milestone Scientific or any other person that the objectives and plans of Milestone Scientific will be achieved. Milestone Scientific undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

PART I

All references in this report to "Milestone Scientific, Inc.," "us," "our," "we," the "Company "or "Milestone" refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Inc. and Milestone Medical Inc. and affiliate, Milestone Education LLC, unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent*®; *CompuMed*®; *CompuFlo*®; *DPS Dynamic Pressure Sensing technology*®; *Milestone Scientific*®; *the Milestone logo*®; *Safety Wand*®; *STA Single Tooth Anesthesia System*®; and *The Wand*®.

Item 1. Business

Overview

Milestone Scientific is a biomedical technology research and development company that patents, designs, develops and commercializes innovative diagnostic and therapeutic injection technologies and devices for medical, dental, cosmetic and veterinary applications. Since our inception, we have engaged in pioneering proprietary, innovative, computer-controlled injection technologies and solutions for the medical and dental markets. We believe our technologies are proven and well established.

We have focused our resources on redefining the worldwide standard of care for injection techniques by making the experience more comfortable for the patient by reducing the anxiety and stress of receiving injections from the healthcare provider. Our computer-controlled injection devices make injections precise, efficient and virtually painless. Milestone's proprietary *DPS* Dynamic Pressure Sensing technology® is our technology platform that advances the development of next-generation devices. It regulates flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, used in various dental and medical injections. It has specific medical applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections.

In 1997, Milestone Scientific released its first commercial product, the first computer-controlled local anesthesia delivery (C-CLAD) system, into the North American marketplace. This product was our proprietary, computer-controlled anesthetic delivery device, initially marketed as *The Wand*®, a computer-controlled local anesthesia delivery (C-CLAD) device with a single-use disposable handpiece for the dental market, regulating and controlling the flow rate of anesthetics. This device, with the addition of several new features, was later re-branded commercially as the *CompuDent*® System.

In 2001, Milestone Scientific was issued the initial United States Patent for *CompuFlo*® technology, entitled "Pressure/Force Computer Controlled Drug Delivery Instrument with Exit Pressure," allowing the device to continuously monitor and control the exit pressure of medication and/or fluid during an injection. We call this innovation *DPS* Dynamic Pressure Sensing technology. This same technology also enables doctors to accurately identify different tissue types based on detecting exit pressure during an injection, facilitating the injection into the correct skin layer. In 2004, the United States Patent Office issued a "Notice of Allowance" for patent protection on two additional critical elements of our *CompuFlo* technology: "Drug Delivery Instrument with Profiles" and "Pressure/Force Computer Controlled Drug Delivery with Automated Charging".

Given our experience and established brand awareness within the dental industry, we elected to focus our initial product development efforts on the integration of *CompuFlo's DPS* Dynamic Pressure Sensing technology into our legacy dental injection device. In 2006, the FDA cleared the first system utilizing *CompuFlo's DPS* Dynamic Pressure Sensing technology— the STA (Single Tooth Anesthesia) System and handpiece for use in the dental market, providing continuous real-time visual and audible pressure feedback from the tip of the needle while also precisely regulating the flow rate. Because of combining the ability to regulate the flow rate and monitor pressure at the tip of the needle, Milestone Scientific developed the industry's first solution for painlessly administering an intra-ligamentary injection, i.e., "*single-tooth anesthesia*" which could be used as the only injection necessary for achieving dental anesthesia, foregoing the need to administer traditional injections such as a nerve branch block. In addition to *single-tooth anesthesia*, the STA System can effectively perform all the traditional injections that dentists routinely give but can provide them virtually pain free and with numerous clinical advantages. This device, which also utilizes a disposable handpiece, is currently marketed by Milestone Scientific as the *Wand STA*® System.

Milestone Scientific believes its dental devices have set a new standard of care for dental injections. Our dental devices have been used to administer tens of millions of injections worldwide. Each of our devices has a related single use disposable handpiece, leading to a continuing revenue stream following sale of the device. At present, we sell disposable handpieces unique to our legacy product (the *Wand* and *CompuDent*) to users who have not upgraded to our current dental product, the *Wand STA* System.

Building on the success of our proprietary, core technology platform for dental injections, and desiring to pursue other growth opportunities, we have recently begun to expand the uses and applications of our proprietary, patented technologies to achieve greater operational efficiencies, enhanced patient safety and therapeutic adherence, patient satisfaction, and improved quality of care across a broad range of medical specialties. In June 2017, we received FDA regulatory clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for certain medical applications. We intend to continue to expand the uses and applications of our *DPS* Dynamic Pressure Sensing technology.

We believe that we and our technology solutions are widely recognized by key opinion leaders (i.e., academics, anesthesiologists and practicing dentists whose opinions are widely respected), industry experts and medical and dental practitioners as a leader in the emerging, computer-controlled injection industry.

Milestone Scientific remains focused on advancing efforts to achieve the following five primary objectives:

- Establishing Milestone's *DPS* Dynamic Pressure Sensing technology platform as the standard-of-care in painless and precise drug delivery, providing for the first time objective visual and audible in-tissue pressure feedback, and continuing to expand platform applications;
- Following obtaining successful FDA clearance of our first medical device in June 2017, Milestone Scientific is transitioning from a research and development organization to a commercially focused medical device company;
- Commercializing our *CompuFlo* Epidural System, a transformative device for epidural anesthesia procedures;
- Expanding the global footprint of our *CompuFlo* Epidural System by partnering with distribution companies worldwide; and
- Continuing the development of our proprietary cosmetic injection device for delivery of botulinum toxin (such as *Botox*® and *Dysport*®).

Our dental devices are sold in the United States, U.S. territories, Canada and in 60 other countries with FDA, CE and other clearances. Since receiving FDA clearance in 2017, our epidural devices have had minimal sales.

***DPS* Dynamic Pressure Sensing Technology; Our Proprietary Core Technology Platform**

Our first commercial product, our proprietary, computer-controlled anesthetic delivery device, initially marketed as the *CompuDent*® Wand/STA system, later re-branded commercially as the *Wand /STA* System, for the dental market, uses patented technology, including a single-use disposable handpiece, to control the flow rate of the anesthesia during the injection, allowing virtually painless injections for all dental procedures with optimal effectiveness. Over the years, the *CompuDent* System has been widely heralded as a revolutionary device, considered one of the major advances in dentistry in the 20th century, and has been favorably evaluated in more than 50 peers reviewed or independent clinical research reports.

Our next significant intellectual property advancement was a quantum improvement over our *CompuDent*® System – the development of our proprietary *CompuFlo*® Computer-Controlled Drug Delivery System with *DPS* Dynamic Pressure Sensing technology, an advanced and FDA-approved technology for the painless and accurate delivery of drugs, anesthetics and other medicaments into all tissue types, as well as for the aspiration of bodily fluids or previously injected substances. Its regulation and control of the flow rate continues to provide painless delivery benefits, while its innovative dynamic pressure sensing capability provides visual and audible in-tissue pressure feedback, identifying tissue types to the healthcare provider. This pressure feedback extends the benefit of painlessness from anesthetics with known viscosities to a wide range of liquid drugs and other medicaments with varying viscosities and flow rates. Such pressure feedback, part of our *DPS* Dynamic Pressure Sensing technology, also allows the healthcare provider to know when certain types of tissues have been penetrated and permits the healthcare provider to inject medicaments precisely at the desired location. Thus, real-time continuous pressure feedback can prevent the injection to tissue outside the intended target area, an important characteristic in the injection of chemotherapeutics and other toxic substances.

In addition to the ability to determine exit pressure *in-situ* (in the injection site tissue) at the tip of the needle, minimizing tissue damage (and eliminating the pain of the injection) because the flow rate and pressure of the injection are precisely controlled, *CompuFlo*® computer-controlled Drug Delivery Systems features a proprietary algorithm, which allow for the measurement of the exit pressure. These algorithms contain the critical components of specific drugs, parameters of needles, tubing and syringes and all other pertinent components for the safe and efficacious delivery of medications for all procedures. *CompuFlo*® technology also enables devices to provide a digital record of the time and volume of anesthetic or medicament injected.

Each CompuDent® and Wand/STA System also includes a disposable injection handpiece that is extremely comfortable, light and easy to use, providing for precise tactile control during the injection, an electro-mechanical (computer-controlled) fluid delivery instrument and the ability to record data from the injection event. The pencil grip used with the handpieces provides the practitioner with enhanced tactile sense and accurate control and allows bi-directional rotation, eliminating needle deflection, resulting in a greater accuracy and success. The handpiece is vibration-free because it does not have a motor or electrical component in it and, since the handpiece does not look like a typical syringe, we believe it also reduces patient anxiety and offers the possibility of curing dental phobia of which an estimated 40 million Americans suffer.

As confirmed by numerous noted medical and dental experts within academia and the clinical practice arenas,*CompuFlo* Systems using *DPS* Dynamic Pressure Sensing technology have the potential to greatly increase the safety and efficacy of many drug delivery procedures that currently rely upon the over 150-year-old hypodermic syringe technology and the tactile senses and delivery expertise of the administrator.

Devices using *DPS* Dynamic Pressure Sensing technology such as the *CompuFlo* System can be used to inject a wide variety of liquid medicaments as well as anesthetics. We believe our *CompuFlo* System avoids the negative side effects from the use of traditional hypodermic drug delivery injection devices, which are well documented in dental and medical literature and include risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications. Pain and tissue damage often result from uncontrolled flow rates and pressure created during the administration of drug solutions into human tissue. While several technologies have can control the flow rate, we believe our patented *DPS* Dynamic Pressure Sensing technology and *CompuFlo* Systems provide the ability to accurately and precisely control the pressure of the injection as well.

We believe our DPS Dynamic Pressure Sensing technology and *CompuFlo* Systems provides the following benefits:

- minimizes the pain associated with injections, resulting in a more comfortable injection experience for the patient;
- provides visual and audible in-tissue pressure feedback, identifying the desired target location to the healthcare provider, extending the benefit of painlessness from anesthetics with known viscosities to a wide range of liquid drugs and other medicaments with varying viscosities and flow rates;
- allows the healthcare provider to know when the target location is present and permits the healthcare provider to inject medicaments precisely at the desired location;
- provides a digital record of the time and volume of anesthetic or medicament injected;
- minimizes tissue damage because the flow rate and pressure of the injection are controlled;
- provides an integrated injection database of algorithms that have been defined which allow for the measurement of the exit pressure, containing the critical components of specific drugs, parameters of needles, tubing and syringes and all other pertinent components for the safe and efficacious delivery of medications;
- the pencil grip used with the handpieces allows significant tactile sense and accurate control;
- new injections made possible with the technology eliminate collateral numbness;
- bi-directional rotation of the handpieces eliminates needle deflection resulting in greater success and more rapid onset of anesthesia in injections; and
- the use of a single patient use, disposable handpieces minimize the risk of cross contamination.

Our first system utilizing a *DPS* Dynamic Pressure Sensing technology platform was our STA System and related handpiece for the dental market, currently marketed as the *Wand/ STA System*. Another platform extension of our *DPS* Dynamic Pressure Sensing technology platform is the *CompuFlo* Epidural System. In addition, we have developed platform extensions of our *DPS* Dynamic Pressure Sensing technology platform for intra-articular (for administering corticosteroids, hyaluronic acid and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions), cosmetic and veterinary applications. We intend to continue to develop and commercialize new applications of our *DPS* Dynamic Pressure Sensing technology platform as commercial line extensions.

***CompuFlo* Epidural Computer Controlled Anesthesia System**

In June 2017, we received FDA regulatory clearance to sell the*CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for certain medical applications. The *CompuFlo* Epidural Computer Controlled Anesthesia System obtained CE mark approval in September 2014, allowing it to be marketed and sold in most European countries and many other countries accepting CE approved devices.

The *CompuFlo* Epidural Computer Controlled Anesthesia System (or the *CompuFlo* Epidural System) is one such platform extension of our *DPS* Dynamic Pressure Sensing technology platform, providing anesthesiologists and other healthcare providers the ability, for the first time, to quantitatively determine and document the pressure at the needle tip in real-time for proper needle placement in epidural procedures used for labor/delivery and back pain management. Our proprietary *DPS* Dynamic Pressure Sensing technology allows the *CompuFlo* Epidural System to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify and confirm placement in the epidural space.

Our *CompuFlo* Epidural System provides an objective tool that we believe consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the intrafilamentary tissue. In studies, the *CompuFlo* Epidural System with *DPS* Dynamic Pressure Sensing technology has been shown to be effective in correctly identifying the epidural space. Knowing the precise location of a needle tip during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes. In the absence of fluoroscopy, identifying the epidural space by relying on the subjective perception of loss of resistance to saline requires a very long education period and learning curve and could result in morbidity and lack of efficacy. During back pain management epidural procedures, where fluoroscopy is commonly used, the *CompuFlo* Epidural System allows the clinician to locate the epidural space, without using fluoroscopy, thereby protecting the patient and clinician from unnecessary exposure to radiation along with significantly reducing capital and operating costs.

An abstract presented at the 45th Chilean Congress of Anesthesiology on November 11, 2017, entitled: Utilization of Dynamic Pressure Sensing™ in Epidural Procedures for Child Birth and representing the first formal presentation of our *CompuFlo* Epidural System in South America, summarized the results of a recent independent, investigator-led clinical study evaluating the use of Milestone's *CompuFlo* Epidural System in 50 labor and delivery patients, concluding that the epidural space was correctly identified in 100% of the patients. In addition, the epidural space was located on the first attempt with all the patients. There were no cases of accidental puncture of the dura, a common risk factor for traditional epidural procedures using the loss of resistance technique. We believe that this represents a significant benefit for the payors, physicians, and most importantly, the patients.

In November 2018, a clinical study published in the International Journal of Obstetric Anesthesia found the *CompuFlo* Epidural System to be successful in objectively identifying the epidural space—even in difficult patients. Accurate epidural space identification can build physician and resident confidence while reducing the number of attempts, poor catheter placement and accidental dural punctures that can be costly to the hospital and painful for the patient.

In January 2019, the Company announced the results of a four hundred patient clinical trial by researchers from the University of Miami, University of Texas and Northwestern University, and two prominent California-based pain clinics. Published-Ahead-of-Print in Anesthesia & Analgesia (the official Journal of the International Anesthesia Research Society), the randomized, controlled study compared the effectiveness of the *CompuFlo* Epidural System in labor and delivery and chronic pain management, where loss of resistance and fluoroscopy are the current standards of care. The *CompuFlo* Epidural System was found to be ninety-nine percent successful in objectively identifying the epidural space even in challenging patients with a higher body mass index.

In February 2019, the Company announced a new 120-patient clinical study published in Anesthesiology Research & Practice that verifies the *CompuFlo* Epidural System consistently differentiates false loss of resistance from true loss of resistance during epidural placement. In all cases where the *CompuFlo* Epidural System's pressure measurements were used to objectively identify the epidural space, the block was performed successfully with no complications.

In February 2019, the Company announced Ospedale "Pugliese Ciaccio" di Catanzaro is the first hospital in Italy to use the *CompuFlo* Epidural System for all epidurals in labor and delivery. For a local hospital performing a limited number of epidurals, the *CompuFlo* Epidural System offers a real-time, objective tool for accurate epidural space identification to help reduce failure rates and accidental dural punctures that can require further treatment and interventions.

In April, 2019 the Company entered the medical education market with the introduction of the CompuFlo® Epidural Trainer (CompuFlo Trainer), an instructional instrument that uses pressure sensing technology to improve epidural placement success. The company has signed an agreement to distribute the CompuFlo Trainer with American 3B Scientific, a leading supplier of didactic material for medical education.

In June 2019 the Company announced the results of two research abstracts featuring the CompuFlo® Epidural device (CompuFlo) at Euroanesthesia 2019, Europe's largest annual event showcasing the latest knowledge in the field of anesthesia. The abstracts were presented during scientific poster sessions highlighting how CompuFlo's objective detection of tissue pressure makes challenging procedures with difficult patients more efficient and accelerates clinical competency for trainee.

In October 2019, the company announced the first international multicenter study to compare the incidence of accidental dural puncture using the CompuFlo® Epidural System versus the continuous loss of resistance (LOR) technique. The study collected records between 2015 and 2019 of epidural administration on labor and delivery patients using the CompuFlo® Epidural System from four institutions, one in the U.S., one in Chile, and two from Italy. Among the four sites, there were 812 patients who received epidural analgesia with CompuFlo® and none had accidental dural puncture regardless of the composition of the epidural performer types. The Company also announced that Professor Rovnat Babazade, MD, University of Texas Medical Branch at Galveston, Department of Anesthesiology, presented a poster at the ANESTHESIOLOGY® 2019 Annual Meeting in Orlando, Florida. The poster, entitled, "International Multicenter Study of Accidental Dural Puncture Rate; Comparison of the CompuFlo with Traditional Method," is available on the Company's website. ANESTHESIOLOGY 2019, hosted by the American Society of Anesthesiologists (ASA), unites more than 14,000 clinicians, thought leaders and professionals from around the world.

In November 2019, the Company and 3B Scientific, the world's leading supplier of didactic material for medical education, signed a global agreement expanding distribution of the CompuFlo® Epidural Trainer (CompuFlo Trainer). The expanded agreement allows 3B Scientific to capitalize on momentum from strong interest in the CompuFlo Trainer at its unveiling at Euroanesthesia 2019 and the Association of Women's Health, Obstetric and Neonatal Nurses meeting, and gives more anesthesia instructors the ultimate solution to accelerate the epidural procedure's learning curve and trainee success.

***CompuFlo* Intra-Articular Computer Controlled Injection System**

Another platform extension utilizing our *DPS* Dynamic Pressure Sensing technology platform and *CompuFlo Epidural* System are our devices for administering corticosteroids and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions. As features of our *DPS* Dynamic Pressure Sensing technology, this device also precisely controls in-tissue pressure, increasing patient safety by reducing the risk of tissue damage and post-treatment pain related to excessive pressure that may occur during certain injections. Identification of the tissue, in which the needle tip is imbedded, is believed to be highly important in intra-articular injections and numerous organs, subcutaneous and intramuscular injections.

We believe our intra-articular injection device is particularly efficacious for arthritis patients who are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious because the doctor using a syringe fails to locate the intra-articular space or does not inject the appropriate volume of corticosteroids or other medicament into that space. Our *CompuFlo* Epidural System has been shown successful in an independent animal study in administering medicaments into a certain intra-articular space using its computer-controlled pressure sensing capabilities.

The intra-articular device has obtained CE mark clearance and may be marketed and sold in most European countries and many other countries accepting CE approved devices. In December 2016, we received notification from the FDA that our 510(k) applications for marketing approval of the intra-articular device did not demonstrate that the device was as safe and effective as a legally marketed device. The original 510-k filed with FDA expired in January 2019. We intended to submit a new 510(k) application in 2019 that we believe would demonstrate substantial equivalency; however, we did not complete this process in 2019 due to a lack of funding. We cannot provide assurances of when funds will be available to complete this process, and if funding becomes available, if ever, that we will receive FDA clearance for our intra-articular device.

We believe that the touch screen and other platform improvements embodied by our cosmetic device will form the basis for our next generation of devices.

Cosmetic Botulinum Injection Device

The American Society of Plastic Surgeons (ASPS) reported that among the 14.2 million cosmetic minimally-invasive procedures performed in 2015, the top performed procedure, at 6.7 million procedures, was Botulinum Toxin Type A (commonly known as Botox) injection. Leveraging our experience in minimizing the pain of dental anesthetic injections, we established a joint venture in 2014 to develop and commercialize a device for the pain free injection of botulinum toxin.

The joint venture entity, Milestone Advanced Cosmetic Systems, Inc., is owned 50% by us and 50% by Milestone China Company Limited ("Milestone China"), a company organized under the laws of Hong Kong and owned 40% by Milestone Scientific. Milestone China contributed $900,000 of cash to the joint venture and we have provided a royalty-free license to utilize our technology to the joint venture to develop a botulinum toxin injection device.

In November 2017, we announced plans for the commercial launch of our proprietary cosmetic injection device using our *DPS* Dynamic Pressure Sensing technology platform and our *CompuFlo* Cosmetic System for delivery of botulinum toxin. Our proprietary cosmetic injection device features improved needle placement with a comfortable stylus grip, precise dosing, the same technology platform that has made dental and epidural injections painless, and a new, intuitive touch-screen interface. Although the Company received positive outcomes of multi-state human factor studies with targeted customers, the Company does not have the necessary capital to move forward with the commercial launch of our cosmetic device and applying for marketing clearance in Europe (CE clearance), and United States (FDA clearance). Although the Company's instrument has progressed beyond the development stage, additional capital is necessary to fund the regulatory process and, if approved the commercialization of the device. To this end, the Company is currently in the process of pursuing additional capital, to pursue such regulatory process. However, the Company can provide no assurance that additional capital will be available on acceptable terms, or at all.

We believe that the touch screen and other platform improvements embodied by our cosmetic device will form the basis for our next generation of devices.

Veterinary Nerve Block Anesthesia Device

The effectiveness of our veterinary nerve block anesthesia device (existing medical device) for such use was confirmed by a pilot study and final report completed by Cornell University, College of Veterinary Medicine. Additional studies with other universities are in process with respect to horses and small animals. We are exploring commercialization opportunities.

The Wand STA System

In 2006, we received FDA clearance for our Wand/STA System and disposable handpiece, the first system utilizing CompuFlo's DPS Dynamic Pressure Sensing technology, for use in the dental market. The Wand/STA System and handpiece continue to provide all of the benefits of the CompuDent System, allowing dentists to provide virtually painless injections for all dental procedures, including routine fillings, as well as more sophisticated implants, root canals and crowns, while better facilitating single tooth anesthesia (now generally performed with a high-pressure spring-loaded gun-like device), but also incorporates the "pressure feedback" elements of Milestone Scientific's patented *CompuFlo*'s DPS Dynamic Pressure Sensing, thereby allowing dentists to administer injections accurately and painlessly into the periodontal ligament space, effectively anesthetizing a single tooth. Injections made by the Wand/STA System eliminate collateral numbness of the tongue, lips and facial muscles and often hasten the onset of anesthesia by eliminating the need for mandibular blocks. The Wand/STA also identifies intrafilamentary tissue, so dentists can find the precise location for single tooth anesthesia. This injection is of significant value in that it allows the dentist to profoundly anesthetize the tooth within one minute per root, versus up to 15-18 minutes for a block injection to take effect. The Wand /STA System can perform all the injections that can be done with a conventional dental syringe, and in addition, we provide the ability to perform the following: the palatal-anterior superior alveolar, anterior middle superior alveolar and inferior alveolar nerve block. The Wand/ STA System achieves these injections predictably and reliably. To date, substantially all our revenue has been generated by the Wand/STA System for dental applications.

Since its market introduction in the spring of 2007, the Wand/STA System has received favorable reviews and awards from the dental industry. In July 2007, noted industry publication Dentistry Today featured the Wand/STA System as one of the "Top 100 Products in 2007", helping to promote much broader recognition of the instrument and validating the Wand/STA System's value proposition for dentists and patients, alike.

In early 2008, Medical Device & Diagnostic Industry magazine distinguished the Wand/STA System as a 2008 Medical Design Excellence Award winner in the "Dental Instruments, Equipment and Supplies" product category. Of the 33 products to receive this coveted award, the Wand/STA System was one of only two winning products that serve dental practitioners.

In December 2008, Milestone Scientific continued to win broad acclaim for the*Wand/STA* System by winning a "Townie Choice Award". The "Townie Choice" awards were originally started by Dr. Howard Darran and Farran Media, publisher of Dentaltown Magazine, to assist dentists in making product purchasing decisions, and are considered the "people's choice" of the products and services available to the dental industry today. That same month, the *Wand/STA* System was also named as a Dental Products Report "Top 100 2008 Product of Distinction". Additionally, the *Wand/STA* System was named one of Dentistry Today's "Top 100 Products" for the third consecutive year in 2010.

Other Devices

At earlier stages of development are our products using *CompuFlo*'s *DPS* Dynamic Pressure Sensing technology for less painful injections for use in rhinoplasty, colorectal surgery, podiatry and other disciplines. In the self-injectable market, there are many injectable drugs routinely self-administered in a home or office setting using spring loaded automatic injection devices by people who suffer from long term chronic conditions such as multiple sclerosis, rheumatoid arthritis, and other diseases of the auto immune system. We believe *CompuFlo*'s *DPS* Dynamic Pressure Sensing technology, using pressure sensing capabilities, can serve as a painless subcutaneous injection method for these self-administered drugs.

However, there can be no assurance that we will be able to successfully develop any such products, or that if developed, that we will be able to obtain FDA approval to market any such products, or even if we do obtain such FDA approval, that any such products will generate any revenue for us or be a commercial success.

Distribution and Marketing Arrangements

Our dental devices are sold in the United States, US territories, Canada and in 60 other countries abroad. In June 2017, we received FDA regulatory clearance to sell our first medical device, the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States. Since receiving FDA clearance in 2017, our epidural devices have had minimal sales in the United States.

Dental Market

In the spring of 2009, Milestone Scientific signed a distribution and marketing agreement with China National Medicines Corporation, dba Sinopharm. In early October 2012, the State Food and Drug Administration ("CFDA") of the People's Republic of China approved the *Wand/STA* System. However, the CFDA's approval of the *Wand STA* handpieces was not received until May 2014 and the distribution of these handpieces in China began in the fourth quarter of 2014.

The distribution and marketing agreement with Sinopharm were terminated in September 2014. Proximate to that time, we entered into a new agreement with Milestone China to be our distributor for the *Wand/STA* System and handpieces in China. Milestone Scientific then owned forty (40%) percent of Milestone China (the "Milestone China Shares"). In June 2017, Milestone Scientific sold its Milestone China Shares to an unaffiliated United States domiciled purchaser for a promissory note secured by a pledge of the Milestone China Shares, and received a 10-year option to repurchase the Milestone China Shares at the same price as the purchase price paid for the Milestone China Shares within the first two years and at fair market value for the remainder of the 10-year term.

In April 2018, such promissory note being in default, Milestone Scientific entered into a Release, Assignment and Termination Agreement (the "Termination Agreement") with the issuer of the promissory note, pursuant to which Milestone Scientific repaid the $250,000 payment made by the issuer, the issuer returned the Milestone China Shares to Milestone Scientific and Milestone Scientific cancelled the promissory note.

In November 2012, Milestone Scientific signed an exclusive distributor and marketing agreement with a well-known U.S. domestic manufacturer and distributor, for the sale and distribution of the *Wand/STA* System and handpieces in the United States and Canada. The marketing initiative included participation in United States and Canadian dental shows, as well as pediatric dental shows; an active advertising initiative targeting major dental publications; and direct mailing campaigns to over 150,000 dentists across the United States and Canada. This exclusive distributor and marketing agreement were converted to a non-exclusive agreement as of December 31, 2016.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, Inc. ("Henry Schein"). In June 2016, that agreement was replaced with an exclusive distribution arrangement for our dental products for the United States and Canada with Henry Schein. Under this arrangement we have a semi-dedicated independent sales force visiting dentists.

To date, Henry Schein has endeavored to accomplish the goals set forth in the exclusive distribution agreement for *The Wand/* STA device and handpieces, including training of its exclusive products sale's specialists. Specifically, up to 35 exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand/*STA device and handpieces and all are currently in the field selling the device.

Henry Schein also increased the number of exclusive product specialist in late 2019 and has agreed to possibly increase the customer service representatives to support dentists across North America through its exclusive product sales customer call center as business volume increases.

On the global front, we have granted exclusive marketing and distribution rights for the Wand/STA Instrument to select dental suppliers in various international regions in Asia, Africa, South America and Europe. They include FM Produkty Dla Stomatologii in Poland and Unident AB in the countries of Denmark, Sweden, Norway and Iceland.

Medical Market

In September 2014, Milestone Medical received CE clearance to distribute its epidural and intra-articular devices in the European Community (EU). Milestone Medical signed a distribution agreement in March 2015 with a medical distributor in Poland for the distribution of the epidural instrument. This distribution agreement was terminated in late 2016 due to the distributor's inadequate performance under the distribution agreement. Milestone Medical is continuing to pursue distributors for the instrument in the EU community.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the CompuFlo System. In June 2017, the FDA approved the CompuFlo System for epidural injections. Beginning in 2020 Milestone Scientific began the process of building an internal sales force to market our epidural instrument to medical schools, hospitals and individual anesthesiologists within the United States and foreign markets. Milestone Scientific's immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k) application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA's Office of Device Evaluation, we filed a new 510(k) application for the device in June 2018. In November 2018, the FDA provided Milestone Scientific with a list of questions on the intra-articular 510(k) application filed in June 2018. Due to the delay in responding to FDA questions, Milestone Scientific will be required to file a new 510(k) application. Milestone Scientific did not complete this process in 2019, due to a lack of funding. We cannot provide assurances of when funds will be available, and if funding becomes available, if ever, that we will receive FDA clearance for our intra-articular device.

In October 2018, Milestone Medical signed a Distributor Agreement in the U.S. This agreement provides that this Distributor will purchase and hold an inventory of the CompuFlo Epidural System and disposables for sale. At this time there have been no minimum purchase established with the Distributor. This Distributor purchased five CompuFlo Epidural Systems and disposables after executing the Agreement.

In April 2019, Milestone Scientific entered an Agreement with American 3B Scientific, a leading supplier of didactic material for education, for the development and sale of a CompuFlo® Epidural Training Instrument. This instructional instrument utilizes the pressure sensing technology and will be utilized as a training instrument to improve epidural placement success. The first sale of this new medical instrument occurred in May 2019, for three instruments and three disposable kits.

We have entered into a limited number of distributor arrangements in Europe and the Middle East for our CompuFlo Epidural System. Our distribution strategy is initially aimed at having KOL's use and accept the device and initiates their own studies.

In September 2019, the Company appointed a new President, Brent Johnston. Mr. Johnston will also be responsible for the growth of the Medical segment. He is evaluating the business and marketing operations of our medical segment to make the changes required to increase market penetration and sales of the epidural device, principally in the United States and other countries. In February 2020, the Company hired two Territory Sales managers to initiate the marker penetration and and sales process in the United States.

Veterinary Market

We are exploring various commercialization opportunities

Patents and Intellectual Property

Milestone Scientific and its subsidiaries currently hold approximately 217 U.S. and foreign patents, and many patent applications. The Company's patents and patent applications relate to drug delivery methodologies, drug flow rate measurement, pressure/force computer-controlled drug delivery with exit pressure, dynamic pressure sensing, automated rate control, automated charging, drug
profiles, audible and visual pressure/force feedback, tissue identification, drug delivery injection unit, drug drive unit for anesthetic, handpiece and injection device. Milestone Scientific and its subsidiaries also currently hold approximately 29 registered U.S. and foreign trademarks, including *CompuDent®, CompuFlo®, DPS Dynamic Pressure Sensing technology®, Safety Wand®, STA Single Tooth Anesthesia System®,* and *The Wand®*

Milestone Scientific relies on a combination of patent, copyright, trade secret and trademark laws and employee and third-party non-disclosure agreements to protect its intellectual property rights. Despite the precautions taken by Milestone Scientific to protect products, unauthorized parties may attempt to reverse engineer, copy, or obtain and use products and information that Milestone Scientific regards as proprietary, or may design products serving similar purposes that do not infringe on Milestone Scientific's patents. Milestone Scientific's failure to protect its proprietary information and the expenses of doing so could have a material adverse effect on our business, financial condition and results of operations.

If Milestone Scientific's products infringe upon patent or proprietary rights of others, we may be required to modify processes or to obtain licenses. There can be no assurance that Milestone Scientific would be able to do so in a timely manner, upon acceptable terms and conditions, or at all. The failure to do so could have a material adverse effect on our business, financial condition and results of operations

Manufacturing

Milestone Scientific has informal arrangements with an US manufacturer of the *Wand/STA* System, epidural and intra-articular devices. Pursuant to these informal arrangements, our third-party manufacturers manufacture the *Wand/STA* System under specific purchase orders without minimum purchase commitments, and at prices to be agreed upon in each such purchase order.
Our agreement with the principal manufacturer of handpieces, a related party, includes pricing terms. Milestone Scientific has been supplied by the manufacturer of the *Wand/STA* System and its predecessor, the *CompuDent* System, since the commencement of production in 1998, and by the manufacturer of its handpieces since 2003. The manufacturer of our handpieces is in the People's Republic of China and the manufacturer of the *Wand/STA* System is in the United States. Refer to Item 1A. Risk Factors

Changes to pricing of the *Wand/STA* System by the manufacturer could have a material adverse effect on our financial condition, business and results of operations. Termination of the manufacturing relationship with any of these third-party manufacturers could significantly and adversely affect our ability to produce and sell the products. Though other alternate sources of supply for handpieces exist, Milestone Scientific would need to establish relationships with new suppliers, and with respect to the *Wand/STA* System recover its existing tools or have new tools produced and "burn in" and other manufacturing and quality control software re-produced. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of supply, whether as a result of the inability of a supplier to meet our product delivery needs or termination of the relationship, would have a material adverse effect on our financial condition, business and results of operations.

Competition

As of this filing, there is no subcutaneous drug delivery platform or device on the market regulating the flow rate*and* pressure of an injection capable of delivering a painless injection at the desired location like Milestone Scientific's proprietary, patented devices having our *DPS* Dynamic Pressure Sensing technology.

Milestone Scientific's devices compete based on their performance characteristics and the benefits provided to the patient, practitioner and their business operations. Clinical studies have shown that our devices reduce fear, pain and anxiety for many patients, and Milestone Scientific believes that they can reduce practitioner stress levels, as well. Other computer-controlled local anesthesia delivery (C-CLAD) options are the Quicksleeper and SleeperOne, from Dental Hi Tec, Dentapen from Septodant, the Calajet from Aseptico, and the Comfort Control Syringe by Dentsply.

The Quicksleeper was invented in France by Dr. Alain Villette in 1991. It is marketed as the only local anesthetic delivery device in France that allows the ability to perform all intraoral local anesthetic injection techniques, including osteocentral anesthesia, quickly and without failure. The extra feature that gives the Quicksleeper this ability is a built-in motor in the syringe/handpiece that renders the syringe both an injector and a perforator of bone. That is, the handpiece of the Quicksleeper can perform an intraosseous injection via a motor driven perforation of the cortical plate of bone. A standard dental needle that attaches to the syringe spins as the motor rotates the handpiece thus acting as a perforator. However, the handpiece is relatively heavy, weighing 240 g. as compared to a standard syringe that weighs 80 g. Injection speed increases during the injection, but the operator cannot control when the injection speed increases.

Another computer-controlled injection instrument is called the Comfort Control Syringe or CCS. In the early 1990's, Dr. Mark Smith, a dentist from Ontario, Canada, invented a device that he incorporated into his practice as a local anesthetic delivery method. After perfecting the system, he assigned the rights of this device to Dentsply. In this system, many of the functions of the computer can be controlled directly from the syringe during the injection process. The base unit allows the dentist to program one of five different injections by pressing a single button. The five buttons marked on the base unit are block, infiltration, PDL, intraosseous and palatal. Each of these injections has a specific corresponding rate of local anesthetic delivery associated with it. The CCS enables a wide range of injection speeds controlled by the operator and the ability to control the computer directly from the syringe, but, since the CCS computer can be controlled by hand, the syringe must contain a certain amount of electronic equipment and this adds bulk to its circumference. The circumference of the CCS syringe is 112mm compared to 36mm for a traditional syringe, and 17mm for the *Wand/STA* System. In addition, because of the electronics in the syringe, the operator will feel a slight amount of vibration in the syringe while the injection occurs. This will not affect the anesthesia, but it certainly is a feeling that is different from the traditional syringe or the *Wand/STA* System, which both have no such vibration. This instrument is no longer being marketed.

The Calajet instrument, manufactured in Europe, has been very slow to grow market acceptance. It recently began marketing in the United States with similar slow acceptance. The instrument is a higher price than the Wand STA and does not provide dynamic pressure sensing technology. Although a competitor, we believe that without a substantial distribution network this instrument will have a difficult time to be successful in the USA.

The Dentapen from Septodent is the newest competitor in the market. This device is manufactured in Europe and began marketing in the USA in 2018. This device is priced similar to the Wand/STA device, but at this time, to our knowledge, it is slow to attract viable distribution in the USA.

Milestone Scientific's proprietary, patented devices with its *DPS* Dynamic Pressure Sensing technology platform also compete with disposable and reusable syringes that generally sell at lower prices and that use established and well-understood methodologies in both the dental and medical marketplaces.

Rapid technological change and research may affect our products. Current or new competitors could, at any time, introduce new or enhanced products with features that render our products less marketable or even obsolete. Therefore, Milestone Scientific must devote substantial efforts and financial resources to improve existing products, bring products to market quickly, and develop new products for related markets. In addition, the ability to compete successfully requires that Milestone Scientific maintain an effective distribution network with a strong marketing plan. Any new products must comply with applicable regulatory authorities before they may be marketed. Milestone Scientific cannot assure that it can compete successfully, that competitors will not develop technologies or products that render our products less marketable or obsolete, or, that Milestone Scientific will succeed in improving its existing products, effectively develop new products, or obtain required regulatory approval for those products.

Government Regulation

The manufacture and sale of medical devices and other medical products are subject to extensive regulation by the FDA pursuant to the U.S. Food, Drug and Cosmetic Act ("FD&C Act"), and by other federal, state and foreign authorities. Under the FD&C Act, medical devices must receive FDA clearance before they can be marketed commercially in the United States. Some medical products must undergo rigorous pre-clinical and clinical testing and an extensive FDA approval process before they can be marketed. These processes can take many years and require the expenditure of substantial resources. The time required for completing such testing and obtaining such approvals is uncertain, and FDA clearance may never be obtained. Delays or rejections may be encountered based upon changes in FDA policy during the period of product development and FDA regulatory review of each product submitted. Similar delays also may be encountered in other countries. Following the enactment of the Medical Device Amendments to the U.S. Food, Drug and Cosmetic Act in May 1976, the FDA classified medical devices in commercial distribution into one of three classes. This classification is based on the controls necessary to reasonably ensure the safety and effectiveness of the medical devices. Class I devices are those devices whose safety and effectiveness can reasonably be ensured through general controls, such as adequate labeling, pre-market notification, and adherence to the FDA's

Quality System Regulation ("QSR"), also referred to as "Good Manufacturing Practices" ("GMP") regulations. Some Class I devices are further exempted from some of the general controls. Class II devices are those devices whose safety and effectiveness reasonably can be ensured using special controls, such as performance standards, post-market surveillance, patient registries, and FDA guidelines. Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and effectiveness. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices.

Pre-market Notification, the manufacturer or distributor may not place the device into commercial distribution until an order is issued by the FDA. By regulation, the FDA has no specific time limit by which it must respond to a 510(k) Pre-market Notification. Currently, the FDA typically responds to the submission of a 510(k) Pre-market Notification within 180 days. The FDA response may declare that the device is substantially equivalent to another legally marketed device and allow the proposed device to be marketed in the United States. However, the FDA may determine that the proposed device is not substantially equivalent or may require further information, such as additional test data, before the FDA is able to decide regarding substantial equivalence. Such determination or request for additional information could delay market introduction of products. If a device that has obtained 510(k) Pre-market Notification clearance is changed or modified in design, components, method of manufacture, or intended use, such that the safety or effectiveness of the device could be significantly affected, separate 510(k) Pre-market notification clearance must be obtained before the modified device can be marketed in the United States. If a manufacturer or distributor cannot establish that a proposed device is substantially equivalent to a legally marketed device, the manufacturer or distributor will have to seek pre-market approval of the proposed device, a more difficult procedure requiring extensive data, including pre-clinical and human clinical trial data, as well as extensive literature to prove the safety and efficacy of the device.

The FDA cleared the Wand, our *CompuDent* System and its disposable handpieces, for marketing in the United States for dental applications in July 1996; the *CompuMed*® System for marketing in the United States for medical applications in May 2001; the *Safety Wand*® for marketing in the United States for dental applications in September 2003; the *Wand/STA* System for dental applications in August 2006; and our *CompuFlo* Epidural System in June 2017. For us to commercialize other products in the United States, Milestone Scientific would have to submit and have cleared additional 510(k) applications to the FDA.

In 2017, the FDA reduced the barrier to marketing clearance for certain dental devices. As a result, other manufacturers of injection devices could more easily enter the dental market. However, we believe that any new device will be very limited in sales volume without a significant distributor in the dental market.

Though certain dental and medical devices have received FDA marketing clearance, there can be no assurance that any of the other medical devices under development will obtain the required regulatory clearance in a timely manner, or at all. If regulatory clearance of a product is granted, such clearance may entail limitations on the indicated uses for which the product may be marketed. In addition, modifications may be made to the products to incorporate and enhance their functionality and performance based upon new data and design review. There can be no assurance that the FDA will not request additional information relating to product improvements; that any such improvements would not require further regulatory review, thereby delaying the testing, approval and commercialization of product improvements; or, that ultimately any such improvements will receive FDA clearance.

Compliance with applicable regulatory requirements is subject to continual review and is monitored through periodic inspections by the FDA. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and criminal prosecution.

Milestone Scientific is subject to pervasive and continuing regulation by the FDA, whose regulations require manufacturers of medical devices to adhere to certain QSR requirements as defined by the FD&C Act. QSR compliance requires testing, quality control and documentation procedures. Failure to comply with QSR requirements can result in the suspension or termination of production, product recall or fines and penalties. Products also must be manufactured in registered establishments. In addition, labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. The export of devices is also subject to regulation in certain instances.

The Medical Device Reporting ("MDR") regulation obligates us to provide information to the FDA on product malfunctions or injuries alleged to have been associated with the use of the product or in connection with certain product failures that could cause serious injury. If, because of FDA inspections, MDR reports or other information, the FDA believes that Milestone Scientific is not in compliance with the law, the FDA can institute proceedings to detain or seize products, enjoin future violations, or assess civil and/or criminal penalties against us, our officers or employees. Any action by the FDA could result in disruption of operations for an undetermined amount of time.

In September 2014 we received CE mark approval for the marketing of the CompuFlo Epidural System, allowing such product to be marketed in most European countries and many other countries accepting CE approved devices.

In April 2017, Milestone Scientific obtained regulatory approval to sell the *CompuFlo* Epidural System and its handpieces in Australia. As of May 2014, the *Wand/STA* System was approved for sale in China. In March 2018, Milestone Scientific obtained regulatory approval to market the *CompuFlo* Epidural System in Canada.

Employees

As of December 31, 2019, the Company had a total 16 full-time employees including three executive officers of Milestone Scientific. Milestone Scientific also has a consultant who serves as a Director of Clinical Affairs and a business development consultant. None of our employees are subject to a collective bargaining agreement and we believe our employee relations are good.

Corporate Information

We were organized in August 1989 under the laws of the State of Delaware. Our principal executive office is located at 425 Eagle Rock Avenue, Roseland, New Jersey 07068, effective January 20, 2020. Prior to January 20, 2020 our principal executive office was located at 220 South Orange Avenue, Livingston, New Jersey 07039. Our telephone number is (973) 535-2717.

Item 1A. Risk Factors

The following factors may affect the growth and profitability of Milestone Scientific and should be considered by any prospective purchaser or current holder of our securities. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks.

We have a history of operating losses that are expected to continue, and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.

We are a small, non-diversified medical device company with a history of limited revenue and significant operating losses and our prospects must be evaluated considering the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. With only one exception (*i.e.,* 2013), we have generated net losses in all periods since the commencement of our operations, including operating losses of approximately $4.0 million and $8.0 million for the years ended December 31, 2019 and 2018, respectively. Overall, at December 31, 2019, we had an accumulated deficit of approximately $93.5 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we undertake to commercialize our *CompuFlo* Epidural System. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product acceptance, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

The report of our independent auditors on our consolidated financial statements for the period ended December 31, 2019 included an emphasis of matter paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our auditors' doubts are based on our recurring losses from operations and working capital deficit. As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to continuing spread of Covid-19, we anticipate that our revenue for the second quarter, and possibly the third quarter, will be materially and adversely affected. At this point in time, it is too early to determine what effect Covid-19 may have on our fourth quarter revenue. Our ability to continue as a going concern will be determined by our ability to generate sufficient revenues from the sale of our products to sustain our operations and/or raise additional capital in the form of debt or equity financing or the sale of assets. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

We require additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate commercialization efforts of our *CompuFlo* Epidural Computer Controlled Anesthesia System.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2019 and 2018, net cash flow used in operations was approximately $1.7 million and approximately $1.6 million, respectively. We expect to continue to spend substantial amounts on commercialization and marketing activities, including the continued commercialization and marketing of our FDA-approved *CompuFlo* Epidural Computer Controlled Anesthesia System. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity financings or corporate collaboration and licensing arrangements, and the sale of non-medical assets.

Raising additional capital by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements or the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Business interruptions, including any interruptions resulting from COVID-19, could significantly disrupt our operations and could have a material adverse impact on our business.

Business interruptions, including any interruptions resulting from COVID-19, could significantly disrupt our operations and could have a material adverse impact on our business. All of our employees are located in the U.S. In addition to our employees, we rely on (i) distributors, agents and third-party logistics providers in connection with product sales and distribution and (ii) raw material and component suppliers in the U.S., Europe and China. If we, or any of these third party partners encounter any disruptions to our or their respective operations or facilities, or if we or any of these third party partners were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute, pandemic or other unforeseen disruption, then we or they may be prevented or delayed from effectively operating our or their business, respectively.

The coronavirus (COVID-19) that was reported to have surfaced in Wuhan, China in December 2019 and that has now spread to other countries throughout the world could adversely impact our operations or those of our third-party partners. Additionally, the continued spread of the virus could negatively impact the manufacture, supply, distribution and sale of our products and our financial results. The extent to which the coronavirus impacts our operations or those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Any losses or damages we incur could have a material adverse effect on our financial results and our ability to conduct business as expected.

Relying exclusively on third parties to manufacture our products, changes in our informal manufacturing arrangements made by the manufacturer of our products and disruptions at the manufacturing facility of our manufacturers and failure to maintain existing supply relationships exposes us to risks that may harm our business.

We have limited internal experience in manufacturing operations and have not historically established our own manufacturing facilities. We currently lack the internal resources to manufacture any of our products, including our *CompuFlo*® Epidural Computer Controlled Anesthesia System.

Milestone Scientific has been supplied by the manufacturer of the Wand/STA System and its predecessor, the CompuDent System, since the commencement of production in 1998, and by the manufacturer of its handpieces since 2003. The manufacturer of our handpieces is in the People's Republic of China and the manufacturer of the Wand/STA System is in the United States. At present, we have an informal arrangement with certain manufacturers of our products. We have one manufacturer of the handpieces for our devices which is under a long-term contract. We have a single manufacturer manufacturing our devices. Our current arrangement with our manufacturers is on a purchase order by purchase order basis. As a result, we do not have price protection or a supply commitment for our devices or handpieces. If either manufacturer insists on a material change in terms or determines to discontinue manufacture of our products, it could have an adverse effect on our financial condition and results of operation.

An operational disruption in the facility of the manufacturer of or their ability to ship our handpieces or devices could negatively impact our financial results. The occurrence of a natural disaster, such as a hurricane, tropical storm, earthquake, tornado, severe weather, flood, fire, or epidemic, pandemic or other health emergency, or other unanticipated problems such as labor difficulties, equipment failure or unscheduled maintenance, in each case could cause operational disruptions of varied duration.

These types of disruptions could materially adversely affect our financial condition and results of operations to varying degrees dependent upon the facility, the duration of the disruption, our ability to shift business to another facility or find alternative sources of supply. Any losses due to these events may not be covered by our existing insurance policies or may be subject to certain deductibles. Given our current manufacturing relationships, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. Our anticipated future reliance on third-party manufacturers exposes us to the following additional risks:

We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to develop substantially equivalent processes for production of our products

- Contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.

- Contract manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact their ability to manufacture our products.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements.

Though other alternate sources of supply for handpieces exist, Milestone Scientific would need to establish relationships with new suppliers, and with respect to the Wand/STA System recover its existing tools or have new tools produced and “burn in” and other manufacturing and quality control software re-produced. Establishing new manufacturing relationships could involve significant expense and delay.

Each of these risks could delay the commercialization of our *CompuFlo* Epidural Computer Controlled Anesthesia System, limit our available supply of The Wand/ STA for dental applications, cause damage to our reputation, result in higher costs and/or deprive us of potential product revenues. Any curtailment or interruptions of the supply, whether as a result of termination of the relationship or otherwise, would have a material adverse effect on our financial condition, business and results of operations.

Our business is exposed to risks associated with the economic, environmental and political conditions in China because the sole manufacturer of our handpieces is located in China.

Because the sole manufacturer of our handpieces is located is located in China, our business is disproportionately exposed to the economic, environmental and political conditions of the region. China’s political and economic systems are very different from most developed countries in many respects, including, the amount of government involvement, the level of development, the control of foreign exchange and the allocation of resources. Uncertainties may arise with changing governmental policies and measures. China also faces many social, economic and political challenges that may produce instabilities in both its domestic arena and in its relationship with other countries.

These instabilities may significantly and adversely affect our supply of handpieces which would in turn adversely affect our financial performance. In addition, as the Chinese legal system develops, there can be no assurance that changes in laws and regulations and their interpretation or their enforcement will not have a material adverse effect on our business relationship with the sole manufacturer of our handpieces. Any adverse change in the economic, environmental and political conditions in China could have a material adverse effect on economic growth and the level of investments and availability of capital in China, which in turn could lead to a reduction in the supply of our handpieces and consequently have a material adverse effect on our businesses.

Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

In general, our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products.

If physicians do not accept nor use our *CompuFlo* Epidural System, our ability to generate revenue from sales will be materially impaired.

Although the FDA has cleared our application to begin marketing the *CompuFlo* Epidural System, this is no assurance that physicians, hospitals, clinics and other health care providers will accept and use it. Acceptance and use of the *CompuFlo* Epidural System will depend on many factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product;
- cost-effectiveness of our product relative to competing products and systems;
- convenience, ease of use and reliability of our product relative to competing products and systems;
- patient satisfaction;
- product availability as well as, manufacturer warranty, maintenance, and customer and technical support;
- availability of reimbursement for our product from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of the *CompuFlo* Epidural Computer Controlled Anesthesia System to generate substantially all our medical product revenues in the near-term, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing or make such financing difficult to obtain on favorable terms, if at all.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The medical device industry is intensely competitive and subject to rapid and significant technological change. We expect that other companies (or individuals), whether located in the United States or abroad, will pursue the development of alternative injection-based or imaging-based systems that will compete with our products. Many of these potential competitors have substantially greater capital resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These companies also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations. As a result, we may not be able to compete effectively against these companies or their products.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The medical device industry is intensely competitive and subject to rapid and significant technological change. We expect that other companies (or individuals), whether located in the United States or abroad, will pursue the development of alternative injection-based or imaging-based systems that will compete with our products.

Many of these potential competitors have substantially greater capital resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These companies also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations. As a result, we may not be able to compete effectively against these companies or their products.

If we are unable to adequately protect our patents, trade secrets and other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged.

Intellectual property rights, including patents, trade secrets, confidential information, trademarks, trade names and trade dress, are important to our business. We will endeavor to protect our intellectual property rights in key jurisdictions in which our products are produced or used and in jurisdictions into which our products are imported. Our success will depend to a significant degree upon our ability to protect and preserve our intellectual property rights. However, we may be unable to obtain or maintain protection for our intellectual property in key jurisdictions.

Although we own and have applied for patents and trademarks throughout the world, we may have to rely on judicial enforcement of our patents and other proprietary rights. Our patents and other intellectual property rights may be challenged, invalidated, circumvented and rendered unenforceable or otherwise compromised. A failure to protect, defend or enforce our intellectual property could have an adverse effect on our financial condition and results of operations. Similarly, third parties may assert claims against us and our customers and distributors alleging our products infringe upon third party intellectual property rights.

We believe that the intellectual property underlying our products is a competitive advantage. We rely on a combination of patent rights, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patents, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the U.S. Patent and Trademark Office. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies resulting from such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

If we must take legal action to protect, defend or enforce our intellectual property rights, any suits or proceedings could result in significant costs and diversion of our resources and our management's attention, and we may not prevail in any such suits or proceedings. A failure to protect, defend or enforce our intellectual property rights could have an adverse effect on our results of operations.

We could lose our market advantage earlier than expected.

We believe that our products represent a significant improvement over any existing drug delivery injection system in use today. However, this competitive advantage can evaporate quickly if we are not able to commercialize our products quickly. In the medical device industry, the majority of an innovative product's commercial value is realized during the early stages of commercialization, before competing products are developed. Our market advantage is based, in part, on patent rights and the need for new competing products and systems to obtain regulatory approval before they can be commercialized. The scope of our patent rights may be limited and may also depend on the availability of meaningful legal remedies.

Our failure to adequately protect our intellectual property rights, through patents or otherwise, or limitations on the use or loss of such rights, could have a material adverse effect on our ability to prevent the commercialization of competing anesthetic delivery systems. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable, and the validity and enforceability of patents cannot be predicted with certainty.

Our failure to adequately protect our intellectual property rights, through patents or otherwise, or limitations on the use or loss of such rights, could have a material adverse effect on our ability to prevent the commercialization of competing anesthetic delivery systems. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable, and the validity and enforceability of patents cannot be predicted with certainty.

Third parties could obtain patents that may require us to negotiate licenses to commercialize our technologies, and we cannot assure you that the required licenses would be available on reasonable terms or at all.

Third parties may claim that one or more aspects of our technologies or products may infringe on their intellectual property rights.

Our computer-controlled anesthesia systems are complex systems and numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of drug delivery systems. In addition, many companies have employed intellectual property litigation as a strategy to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the U.S. and in foreign jurisdictions. If any of our computer-controlled anesthesia systems are found to infringe third party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent.

We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign the system to avoid infringement. Even if we can redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or costlier product. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminary or permanently prohibit us, our licensees, if any, and our customers from making, using, selling, offering to sell or importing one or more of our products or using our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

We are exposed to the risks inherent in international manufacturing, sales and operations.

In 2019, export sales outside of the United States made up approximately 46% of our total sales, and we sell our products to customers in approximately 62 countries and US territories . We have exposure to risks of operating in many foreign countries, including:

- fluctuations in foreign currency exchange rates, could increase the end user cost for instruments;
- restrictions on, or difficulties and costs associated with, the currency exchange from foreign countries to obtain US dollars;
- difficulties and costs associated with complying with a wide variety of complex laws, treaties and regulations;
- unexpected changes in political or regulatory environments;
- political and economic instability;
- import and export restrictions and other trade barriers; and
- difficulties in obtaining approval for significant transactions.

Continued instability in the credit and financial markets may negatively impact our ability to commercialize our products

Financial markets in the United States, Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be reduced. As a small medical device company, we rely on third parties for several important aspects of our business, including contract manufacturing of products, distribution of our products and sales and marketing. These third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued volatility in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of any adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

Our ability to commercialize our products will depend in part on the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers.

Our ability to generate revenues from our products will be diminished if the products sell for inadequate prices or hospitals or physicians are unable to obtain adequate levels of reimbursement for the cost they incur in connection with the use of the product. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Insurance coverage may not be available, or reimbursement levels may be inadequate, to cover the charges for the use of such product. If government and other healthcare payers do not provide adequate coverage and reimbursement for any of our products, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and price controls. In the United States, where pricing levels for medical products, procedures and services are substantially established by third-party payors, including Medicare, if payors reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue use of the product, to substitute lower cost products even if the alternatives are less effective or to seek additional price-related concessions. These actions could have a negative effect on our financial results. The existence of direct and indirect price controls and pressures on our products could materially adversely affect our financial prospects and performance.

We are subject to substantial domestic and international government regulation, including regulatory quality standards applicable to our manufacturing and quality processes. Failure by us to comply with these standards could have an adverse effect on our business, financial condition or results of operations.

The FDA regulates the approval, manufacturing and sales and marketing of many of our products in the United States. Significant government regulation also exists in other countries in which we conduct business. As a device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA.

In the European community, we are required to maintain certain ISO certifications to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Failure to comply with current governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages or delays in product manufacturing. Efficacy or safety concerns, an increase in trends of adverse events in the marketplace, and/or manufacturing quality issues with respect to our products could lead to product recalls or related field actions, withdrawals, and/or declining sales.

We may be subject, directly or indirectly, to U.S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.

Our operations are and will continue to be directly, or indirectly through our distributors, customers and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, and the Foreign Corrupt Practice Act of 1977 ("FCPA"). These laws may impact, among other things, our proposed sales, and marketing and education programs. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as the federal False Claims Act. Many states have also adopted laws like the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "relators" or "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and health care companies to have to defend False Claim Act actions. The Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been previously dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws with qui tam provisions.

The Affordable Care Act includes provisions known as the Physician Payments Sunshine Act (section 6002), which require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to disclose to the Centers for Medicare and Medicaid Services any transfers of value to physicians and teaching hospitals. Manufacturers must also disclose investment interests held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to $1 million per year for knowing violations and may result in liability under other federal laws or regulations

Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states, such as Massachusetts and Vermont, impose an outright ban on certain gifts to physicians. These laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our products. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, or an administrative action of suspension or exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations.

In addition, we are subject to the Foreign Corrupt Practices Act ("FCPA") and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, results of operations and financial condition.

We may be subject to product liability claims that are not fully covered by insurance and that could put Milestone Scientific under financial strain.

Milestone Scientific could be subject to claims for personal injury from the alleged malfunction or misuse of the dental and medical products. While Milestone Scientific carries liability insurance that is believed to be adequate, there is no assurance that the insurance coverage will be sufficient to pay such claims should they be successful. A partially or completely uninsured claim, if successful and of significant magnitude, could have a material adverse effect on our business, financial condition and results of operations.

Excessive returns under our Exclusive Distribution and Supply Agreement with Henry Schein, Inc. could have a material adverse effect on our business, financial condition and results of operations.

In June 2016, we entered into a new exclusive distribution and supply agreement with Henry Schein pursuant to which they were appointed as the exclusive distributor for our dental products in the United States and Canada. Under that agreement, Henry Schein has a right to return our products for full credit against the purchase price paid by them under limited circumstances in accordance with such agreement, including but not limited to, returns due to shipment error by us or factory defect. Excessive returns during any calendar year could have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and regulations over which we have no control can significantly affect our business and results of operations.

Any governmental entity that regulates our operations in the country in which they are located may enact new legislation or adopt new laws and regulations or policies at any time, and new judicial decisions may change the interpretation of existing legislation or regulations at any time in any of the countries in which our operations or projects are located. We have no control over any such changes. Any new laws or regulations governing our operations could have an adverse impact on our business, results of operations and prospects.

We rely on the continuing services of our Interim Chief Executive Officer and Director of Clinical Affairs.

We depend on the personal efforts and abilities of our Interim Chief Executive Officer and Director of Clinical Affairs. Milestone Scientific maintains a key man life insurance policy in the amount of $1,000,000 on the life of its Interim Chief Executive Officer. However, the loss of his services or the services of our Director of Clinical Affairs, on whom we maintain no insurance, could have a materially adverse effect on our business results of operations and prospects.

Milestone Scientific is effectively controlled by a limited number of stockholders.

Milestone Scientific's principal stockholders, Leonard Osser, Gian Domenico Trombetta and K. Tucker Andersen beneficially own approximately 35.5% of the issued and outstanding shares of common stock. As a result, they can exercise substantial control over our affairs and corporate actions requiring stockholder approval, including electing directors, selling all or substantially all our assets, merging with another entity or amending our certificate of incorporation. This control could delay, deter or prevent a change in control and could adversely affect the price that investors might be willing to pay in the future for Milestone Scientific's securities. In addition, because of the concentration of ownership of our shares of common stock, our stockholders may from time to time, observe instances where there may be less liquidity in the public markets for our securities.

Failure to implement effective internal controls required by the Sarbanes-Oxley Act of 2002 could result in material misstatements in our financial statements, cause investors to lose confidence in the Company's reported financial information and have a negative effect on the trading price of our common stock.

Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual and interim financial statements will not be prevented or detected on a timely basis. Any failure to complete the Company's assessment of its internal controls over financial reporting or to remediate any material weaknesses that management may identify could harm the Company's operating results, cause the Company to fail to meet its reporting obligations or result in material misstatements in the Company's financial statements. Inadequate disclosure controls and procedures and internal controls over financial reporting could also cause investors to lose confidence in the Company's public disclosures and reported financial information, which could have a negative effect on the trading price of our common stock.

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility because of many factors, including:
our failure to meet analysts' expectations.

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating our strategy to commercialize our*CompuFlo* Epidural System;
- the success of our strategy to commercialize our*CompuFlo* Epidural System;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions that could adversely impact the market acceptance or competitive advantages of our *CompuFlo* Epidural System;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- our ability to successfully develop and commercialize products and services for the healthcare industry;
- conditions in the medical device industry;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for small, medical device companies have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

Almost all our 49,410,176 outstanding shares of common stock at December 31, 2019 , as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either freely or pursuant to Rule 144 under the Securities Act of 1933, as amended. In addition, we have an effective S-3 registration statement on file with the SEC covering the sale by us of up to $30 million of securities, including common stock, preferred stock, debt, convertible debt and warrants. In February 2019 we issued 6,282,400 shares and 1,570,600 warrants to purchase common shares under our S-3 registration statement. During 2019 the Company issued 639,375 shares associated the warrants issued in February 2019. Since the year ended December 31, 2019, the Company issued 675,000 shares of common stock for warrants exercised at $0.50 for proceeds of $337,500. Additionally, in a private placement we issued 714,286 restricted common shares and 178,571 warrants to purchase common stock. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Provisions in our certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors; and

    - limitations on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The existence of the forgoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

If we fail to adhere to the strict listing requirements of NYSE American, we may be subject to delisting. As a result, our stock price may decline, and our common stock may be de-listed. If our stock were no longer listed on NYSE American, the liquidity of our securities likely would be impaired.

Our common stock currently trades on the NYSE American under the symbol “MLSS”. If we fail to adhere to NYSE American's strict listing criteria, including with respect to stock price, our market capitalization and stockholders’ equity, our stock may be de-listed. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. Any failure at any time to meet the continuing NYSE American listing requirements could have an adverse impact on the value of and trading activity in our common stock.

Currently we are not in compliance with NYSE America Exchange, Stockholder Equity listing requirements. We filed a plan to regain compliance in December 2018, which the NYSE American Exchange has accepted. Under the plan, we will review our progress to regain compliance with the staff of the Exchange on a periodic timetable during the period covered by the plan. Failure to adhere to the plan or regain compliance status with NYSE America Exchange requirements will result in the Company's shares being delisted from NYSE American Exchange.

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Property

The headquarters for Milestone Scientific is located at 425 Eagle Rock Avenue, Roeland, New Jersey 07068, effective January 20, 2020. Prior to January 20, 2020 our principal executive office was located at 220 South Orange Avenue, Livingston, New Jersey 07039 and our telephone number is (973) 535-2717. In August 2019, the Company made the decision to not renew the existing office lease in Livingston, New Jersey and instead signed a seven (7) year lease in a new facility in Roseland, New Jersey (the “Roseland Facility”). The Roseland Facility carries monthly lease payments of $9,275, commencing April 1, 2020.The Company is also responsible for electric charges equal to $2.00 per square foot, which is equal to $11,130 annually, payable in equal monthly installments of $928.00. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts. A third-party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

Milestone Scientific does not own or intend to invest in any real property. Milestone Scientific currently has no policy with respect to investments or interests in real estate, real estate mortgages or securities of, or interests in, persons primarily engaged in real estate activities.

Item 3. Legal Proceedings

Milestone Scientific is not involved in any material litigation.

Item 4. Mine Safety Disclosure

Not applicable.

PART II

Item 5. Market for Common Equity, and Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

Market Information

On June 1, 2015, our common stock was listed on the NYSE American under the symbol “MLSS”. The following table sets forth the high and low sales prices of Milestone’s common stock for the periods presented

2019	High	Low	2018	High	Low
First Quarter	$ 0.87	$ 0.29	First Quarter	$ 1.19	$ 0.72
Second Quarter	$ 0.51	$ 0.31	Second Quarter	$ 0.94	$ 0.65
Third Quarter	$ 1.02	$ 0.37	Third Quarter	$ 0.89	$ 0.71
Fourth Quarter	$ 1.68	$ 0.72	Fourth Quarter	$ 0.75	$ 0.28

Holders

As of March 30, 2020, we had approximately 99 stockholders of record of our common stock. We believe that we have approximately 3,364 beneficial owners of our common stock.

Dividends

The holders of common stock are entitled to receive such dividends as may be declared by Milestone Scientific’s Board of Directors. Milestone Scientific has not paid and does not expect to declare or pay any dividends in the foreseeable future.

Sales of Unregistered Securities

See NOTE I – STOCKHOLDERS’ EQUITY, to the audited consolidated financial statements that accompany this Report for information regarding the issuance of unregistered securities. These issuances were exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act") and a legend restricting the sale, transfer, or other disposition of these shares other than in compliance with the Act was imprinted on stock certificates evidencing the shares.

During the year ended December 31, 2019 the Company issued 316,824 shares of common stock in payment of $123,000 of consulting expenses incurred by the Company.

The foregoing shares were issued in reliance upon the exemptions from the registration requirements of the Securities Act of 1933, as amended (the "Act"), pursuant to Sections 4(a)(2), Section 4(a)(5) and/or Regulation D promulgated there-under. These securities may not be offered or sold in the United States absent registration under or exemption from the Act and any applicable state securities laws. A legend restricting resale, transfer, or other disposition of these shares other than in compliance with the Act was imprinted on the stock certificates evidencing such shares.

ITEM 6. Selected Financial Data

Milestone Scientific is a “smaller reporting company” as defined by Regulations S-K and as such, is not required to provide the information contained in this item pursuant to Regulation S-K.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussions of the financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this annual report. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Exchange Act, that involve risks and uncertainties. The actual results may differ materially from those anticipated in these forward-looking statements. See "Risk Factors" elsewhere in this Form 10-K.

OVERVIEW

Our common stock was listed on the NYSE American on June 1, 2015 and trades under the symbol "MLSS". We have developed a proprietary, computer-controlled anesthetic delivery instrument, using *The Wand*, a single use disposable handpiece. The instrument is marketed in dentistry under the trademark*CompuDent*®, and *STA Single Tooth Anesthesia System* and in medicine under the trademark *CompuMed. CompuDent* is suitable for all dental procedures that require local anesthetic.*CompuMed* is suitable for many medical procedures regularly performed in plastic surgery, hair restoration surgery, podiatry, colorectal surgery, dermatology, orthopedics and several other disciplines. The dental instruments are sold in the United States, US territories, Canada, and in over 58 other countries abroad. In June 2017, the FDA approved our 510(k) applications for marketing clearance in the United States of our *CompuFlo* Epidural System. We are in the process of introductory meetings with medical device distributors within the United States and Europe. There have been ten medical instruments sold in the United States through December 2019, and limited amounts sold internationally as of the reporting date. Certain of our medical instruments have obtained European CE mark approval and can be marketed and sold in most European countries.

In November 20, 2018, Milestone Scientific Inc. received a letter from NYSE American LLC (the "Exchange") stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the "Company Guide").On December 20, 2018, the Company submitted a plan of compliance (the "Plan") to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020.

On January 24, 2019, the Company received a letter from the Exchange stating that the Company's Plan has been accepted by the Exchange. The Company is still not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide and its listing on the Exchange is being continued pursuant to an extension granted by the Exchange. If the Company is not in compliance with the continued listing standards by May 20, 2020, or if the Company does not make progress consistent with the Plan, the Exchange will initiate delisting procedures as appropriate. The Company may appeal a staff delisting determination in accordance with Section 10 and Part 12 of the Company Guide.

In 2019, we remained focused on advancing efforts to achieve our three primary objectives; in our Medical sector; those being:

- Identify distributors in the United States for the Epidural instruments, now that FDA clearance has been received;
- Worldwide distribution of the *CompuFlo* Epidural System; and
- Complete the Cosmetic device and obtain European Regulatory Approve (CE market clearance).

Wand STA Dental Instrument Growth

Since its market introduction in early 2007, the Wand/STA Instrument and prior C-CLAD products have been used to deliver over 66 million safe, effective and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

Global Distribution Network

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, Inc. ("Henry Schein"). In June 2016, that agreement was replaced with an exclusive distribution arrangement for our dental products for the United States and Canada with Henry Schein. Under this arrangement we have a semi-dedicated independent sales force visiting dentists.

To date, Henry Schein has endeavored to accomplish the goals set forth in the exclusive distribution agreement for *The Wand/* STA device and handpieces, including training of its exclusive products sale's specialists. Specifically, up to 25 exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand/*STA device and handpieces and all are currently in the field selling the device.

Henry Schein also increased the number of exclusive product specialist in late 2019 and has agreed to possibly increase the customer service representatives to support dentists across North America through its exclusive product sales customer call center as business volume increases.

On the global front, we have granted exclusive marketing and distribution rights for the Wand/STA Instrument to select dental suppliers in various international regions in Asia, Africa, South America and Europe. They include FM Produkty Dla Stomatologii in Poland and Unident AB in the countries of Denmark, Sweden, Norway and Iceland.

In October 2012, the State Food and Drug Administration (CFDA) of the People's Republic of China approved our Wand/STA *Single Tooth Anesthesia System* (STA System). In May 2014, the CFDA also approved the Wand STA handpieces for sale in China.

In June 2014, Milestone Scientific invested $1 million in Milestone China Ltd. ("Milestone China") by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting. Milestone China became the Company exclusive distributor of dental products in China. As of December 31, 2019 and 2018, Milestone Scientific's investment in Milestone China was $0. As of December 31, 2019 and 2018, Milestone Scientific's share of cumulative suspended losses of Milestone China were $4,574,125 and $3,380,388, respectively.

In September 2014, Milestone Medical received CE clearance to distribute their epidural and intra-articular instruments in the European Community (EU). Milestone Medical signed a distribution agreement in March 2015 with a medical distributor in Poland for the distribution of the epidural instrument. This distribution agreement was terminated in late 2016 due to the distributor's inadequate performance under the distribution agreement. Milestone Medical is continuing to pursue distributors for the instrument in the EU community.

The following table shows a breakdown of Milestone Scientific's product sales (net), domestically and internationally, by business segment product category:

	2019		
Domestic: US/Canada	**Dental**	**Medical**	**Grand Total**
Instruments	$ 693,767	$ 10,800	$ 704,567
Handpieces	3,733,208	2,900	3,736,108
Accessories	85,930	-	85,930
Grand Total	$ 4,512,905	$ 13,700	$ 4,526,605
International: Rest of World	**Dental**	**Medical**	**Grand Total**
Instruments	$ 1,241,860	$ 8,000	$ 1,249,860
Handpieces	2,360,178	15,900	2,376,078
Accessories	63,308	-	63,308
Grand Total	$ 3,665,346	$ 23,900	$ 3,689,246
International: China	**Dental**	**Medical**	**Grand Total**
Instruments	$ 45,750	$ -	$ 45,750
Handpieces	112,900	-	112,900
Accessories	-	-	-
Grand Total	$ 158,650	$ -	$ 158,650
Total Product Sales	$ **8,336,901**	$ **37,600**	$ **8,374,501**

	2018		
Domestic: US/Canada	**Dental**	**Medical**	**Grand Total**
Instruments	$ 491,375	$ 32,500	$ 523,875
Handpieces	4,211,243	-	4,211,243
Accessories	96,088	-	96,088
Grand Total	$ 4,798,706	$ 32,500	$ 4,831,206

International: Rest of World	**Dental**	**Medical**	**Grand Total**
Instruments	$ 1,292,844	$ 81,000	$ 1,373,844
Handpieces	2,444,639	6,100	2,450,739
Accessories	66,087	200	66,287
Grand Total	$ 3,803,570	$ 87,300	$ 3,890,870

International: China	**Dental**	**Medical**	**Grand Total**
Instruments	$ 109,374	$ -	$ 109,374
Handpieces	790,626	-	790,626
Accessories	-	-	-
Grand Total	900,000	-	900,000
Total Product Sales	$ **9,502,276**	$ **119,800**	$ **9,622,076**

Current Product Platform

See Item 1. Description of Business.

Summary of Critical Accounting Policies and Significant Judgments and Estimates

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, Milestone Scientific evaluates its estimates, including those related to accounts receivable, inventories, stock-based compensation and contingencies. Milestone Scientific bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not clear from other sources. Actual results may differ from those estimates under different assumptions or conditions.

While significant accounting policies are more fully described in Note C to the consolidated financial statements included elsewhere in this report, Milestone Scientific believes that the following accounting policies and significant judgment and estimates are most critical in understanding and evaluating the reported financial results.

Principles of Consolidation

Milestone Scientific's discussion and analysis of the financial condition and results of operations is based upon its consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of its wholly-owned and majority-owned subsidiaries including, Wand Dental, Milestone Advanced Cosmetic and Milestone Medical. Milestone Education was a variable interest entity of which Milestone Scientific was the primary beneficiary and is consolidated into Milestone Scientific's financial statements. Milestone Scientific purchased the remaining 50% of Milestone Education in September 2018 for $1.00 increasing its ownership of Milestone Education to 100%. All significant, intra-entity transactions and balances are eliminated in the consolidation. Milestone Scientific invested $1 million in Milestone China Ltd. (“Milestone China”) by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting.

Milestone Scientific has a variable interest in Milestone China, it considered the guidance in ASC 810, “Consolidation” as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

- Power Criterion: The power to direct the activities that most significantly impact the entity's economic performance; and
- Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE

Milestone Scientific does not have the ability to control the activities that most significantly impact Milestone China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of Milestone China to the CEO and a group of significant shareholders, including the Milestone China CEO, of Milestone China which have the power to direct the activities that most significantly impact the economic performance of Milestone China. Management has concluded that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and continues to be accounted for under the equity method. See Note F.

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, Milestone Scientific evaluates its estimates, including those related to accounts receivable, inventories, stock-based compensation and contingencies. Milestone Scientific bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not clear from other sources. Actual results may differ from those estimates under different assumptions or conditions.While significant accounting policies are more fully described in Note C to the consolidated financial statements included elsewhere in this report, Milestone Scientific believes that the following accounting policies and significant judgment and estimates are most critical in understanding and evaluating the reported financial results.

Assessment of our Ability to Continue as a Going Concern

In accordance with Accounting Standard Codification ("ASC") 205-40, "Presentation of Financial Statements – Going Concern", the Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception. Based on the expected cash needed for operating activities, the Company's current cash and liquidity is not sufficient to finance the operating requirements for at least the next 12 months from the filing date of this annual report. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses. The Company's continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability, if ever. Milestone Scientific raised capital in February 2019 in a public and private offering in the aggregate gross proceeds of approximately $2.45 million. Management is actively pursuing financing or other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all.

The consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recover ability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern.

Other Uncertainties

As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of Covid-19, we anticipate that our revenue for the second quarter, and possibly the third quarter, will be materially and adversely affected. At this point in time, it is too early to determine an estimate of what the second or third quarter impact will be or the effect Covid-19 may have on our fourth quarter revenue. In addition, it is too early to determine what the effect will be on the anticipated commercialization of our Compuflow Epidural system as a medical device.

Accounts Receivable

Milestone Scientific sells a significant amount of its products on credit terms to its major distributors. Milestone Scientific estimates losses from the ability or inability of its customers to make payments on amounts billed. Most of credit sales are due within ninety days from invoicing.

Inventories

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or net realizable value. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirement and regulations.

Impairment of Long-Lived Assets

Milestone Scientific reviews long-lived assets for impairment whenever events or circumstances (i.e. a triggering event) indicate that the carrying amounts may not be recoverable.

The Company's impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

- significant under performance relative to expected historical or projected future operating results,
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business
- significant negative industry or economic trends
- significant technological changes, which would render the technology obsolete

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs. At December 31, 2018 , Milestone Scientific identified certain patents purchased in 2017 that will not be further developed and commercialized before the estimated useful life expires and, as such, an impairment charge was recorded. No such charge was incurred during the year ended December 31, 2019.

Revenue Recognition

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps:

i. identification of the promised goods or services in the contract;
ii. determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
iii. measurement of the transaction price, including the constraint on variable consideration;
iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606.

The Company derives its revenues from the sale of its products, primarily dental instruments, handpieces, and other related products. The Company sells its products through a global distribution network and that includes both exclusive and non-exclusive distribution agreements with related and third parties.

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Results of Operations

The following table sets forth the consolidated results of operations for the year ended December 31, 2019 compared to 2018 . The trends suggested by this table may not be indicative of future operating results:

	2019	2018
Operating results:		
Product sales, net	$ 8,374,501	$ 9,622,076
Cost of products sold	2,656,142	5,190,775
Gross profit	5,718,359	4,431,301
Operating expenses:		
Selling, general and administrative expenses	9,527,429	10,645,206
Research and development expenses	189,923	245,636
Impairment to long lived assets	-	1,539,794
Loss from operations	(3,998,993)	(7,999,335)
Other income, and loss on earning net	54,333	307,364
Change in fair value of derivative liability	(3,635,580)	-
Net loss	(7,580,240)	(7,691,971)
Net loss attributable to noncontrolling interests	(55,872)	(260,126)
Net loss attributable to Milestone Scientific Inc.	$ (7,524,368)	$ (7,431,845)

Cash flow:	December 31, 2019	December 31, 2018
Net cash used in operating activities	$ (1,779,288)	$ (1,628,106)
Net cash used in investing activities	(9,916)	(15,421)
Net cash provided by financing activities	2,562,047	(250,000)

Year ended December 31, 2019 compared to year ended December 31, 2018

Net sales for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	$ 8,336,901	$ 9,502,276	$ (1,165,375)	-12%
Medical	37,600	119,800	(82,200)	-69%
Total sales, net	$ 8,374,501	$ 9,622,076	$ (1,247,575)	-13%

Consolidated revenue for the twelve months ended December 31, 2019 and 2018 were approximately $8.4 million and $9.6 million, respectively. Dental revenue for the twelve months ended December 31, 2019 and 2018 were approximately $8.3 million and $9.5 million, respectively. Dental revenues decreased by approximately $1.2 million, which was related to a decrease in sales to China of approximately $741,000, decreased devices and handpiece sales in the United States and Canada by approximately $256,000, and a decrease in international sales by approximately 118,000 in 2019 compared to 2018. The reduction in shipments to Milestone China is due to Milestone China continuing cash flow issues and the modification to their business strategy to better serve the China dental market. Domestic inventory purchases by Henry Schein have been reduce due to lower target inventory model within Henry Schein. However, in the domestic market, our exclusive distribution agreement with Henry Schein continues to pay off as the sell through has been consistent.

Medical revenue for the twelve months ended December 31, 2019 and 2018, were approximately $38,000 and $120,000, respectively. In June 2017, the Company announced that the *CompuFlo* Epidural System received 510(k) marketing clearances from the U.S. Food and Drug Administration (FDA). Milestone is in the process of attending medical device trade shows and attending introductory meetings with medical device distributors within the United States and European markets. The Company is focusing the marketing its Epidural devices principally in the United States. In 2020, the Company began to build an internal sales force to market the Epidural devices to hospitals and medical center throughout the United States.

As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of Covid-19, we anticipate that our revenue for the second quarter, and possibly the third quarter, will be materially and adversely affected. At this point in time, it is too early to determine an estimate of what the second or third quarter impact will be or the effect Covid-19 may have on our fourth quarter revenue. In addition, it is too early to determine what the effect will be on the anticipated commercialization of our Compuflow Epidural system as a medical device in 2020

Gross Profit for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	$ 5,706,658	$ 4,580,753	$ 1,125,905	25%
Medical	11,701	(149,452)	161,153	-108%
Total gross profit	$ 5,718,359	$ 4,431,301	$ 1,287,058	29%

Consolidated gross profit for the twelve months ended December 31, 2019 and 2018 were approximately 68% and 46%, respectively. Dental gross profit for the twelve months ended December 31, 2019 and 2018 were approximately $5.7 million (68%) and $4.6 million (48%), respectively. Dental gross margin for the twelve months ended December 31, 2019 increased due higher selling prices, de minims inventory reserves, and a credit for 2018 recovery of ($151,000) leaky handpieces. During 2018 the Company recorded a reserve of approximately $1.2 million for the underlying inventory associated with deferred cost due to Milestone China's market under performance and liquidity constraints. The Medical gross profit in 2018 was impacted by a reserve of $234,350 for slow moving intra-articular medical instruments due to the continued delay of the intra- articular regulatory approval.

Selling, general and administrative expenses for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	$ 2,930,928	$ 3,207,575	$ (276,647)	-9%
Medical	2,171,881	2,369,290	(197,409)	-8%
Corporate	4,424,620	5,068,341	(643,721)	-13%
Total selling, general and administrative expenses	$ 9,527,429	$ 10,645,206	$ (1,117,777)	-11%

Consolidated selling, general and administrative expenses for the twelve months ended December 31, 2019 and 2018, were approximately $9.5 million and $10.6 million, respectively. The decrease of approximately $1.1 million is related to a decrease stock based compensation, amortization, and professional fees of approximately $1.3 million offset by an increase in travel, marketing, executive compensation, and quality control expenses of approximately $190,000 for the twelve months ended December 31, 2019 compared to 2018.

Research and Development for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	$ -	$ -	$ -	0%
Medical	189,923	92,489	97,434	105%
Corporate	-	153,147	(153,147)	-100%
Total research and development	$ 189,923	$ 245,636	$ (55,713)	-23%

Consolidated research and development expenses for the twelve months ended December 31, 2019 and 2018, were approximately $190,000 and $245,000, respectively. The decrease is due to management discretion and curtailment in the development of several new projects that were being worked on during 2018. In 2019, management decided to make modifications to some Epidural devices for the development of an Epidural trainer devices, the CompuFlo® Epidural Trainer (CompuFlo Trainer), an instructional instrument that uses pressure sensing technology to improve epidural placement success. The CompuFlo Epidural Trainer is for training purposes only and not intended for clinical use.

Profit (Loss) from Operations for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	$ 2,775,716	$ 1,373,178	$ 1,402,538	102%
Medical	(2,350,103)	(2,611,231)	261,128	-10%
Corporate	(4,424,606)	(6,761,282)	2,336,662	-35%
Total loss from operations	$ (3,998,993)	$ (7,999,335)	$ 4,000,328	-50%

The loss from operations was approximately $3.9 million and $7.9 million or the twelve months ended December 31, 2019 and 2018, respectively, a decrease of $4.0 million. 2019 included an increase in gross profit dollars of approximately $1.3 million. As noted above, in 2018, Milestone Scientific charged approximately $1.5 million to the corporate segment for an impairment of long-lived assets (Apad patents). The Company also recorded a reserve for slow moving inventory of approximately $289,000 and a reserve of approximately $273,000 for certain dental handpieces during third quarter 2018. The dental segment of the business continues to control expenses and provided a profit for the period. Costs in the medical segment are increasing as personnel are hired in the U.S. to focus on our domestic Epidural device business.

Change in Derivative Liability

In 2019, the Company incurred a non-cash expense of approximately $3.65 million due to the shares and warrants issued in the public and private offerings as well as other issuance of common stock during 2019 for which the Company did not have a sufficient number of authorized shares of common stock to cover the exercise and issuance of approximately 5,850,000 outstanding equity instruments. All warrants issued in the public and private placements during 2019 and 2016, all shares-to-be-issued, and certain employee options were classified as liabilities during part of year ended December 31, 2019. The Company received shareholder approval to increase the number of authorized shares of common stock on December 17, 2019. At that time the Company extinguished the liability for insufficient number of authorized shares of common stock. At December 31, 2019, all outstanding warrants, shares to be issued and options are not classified as a liability.

After the impact of the derivative liability, the Net Loss was approximately $7.5 million and $7.4 million for the twelve months ended December 31, 2019 and 2018, respectively, an increase in net loss of approximately $0.1 million.

Liquidity and Capital Resources

At December 31, 2019, Milestone Scientific had cash and cash equivalents of approximately $1.5 million and working capital of approximately $1.2 million versus working capital of $1 million in 2018. For the twelve months ended December 31, 2019 and 2018, we had negative cash flows from operating activities of approximately $1.8 million and $1.6 million, respectively. Based on current and expected cash to be used in operating activities substantial doubt exists about the Company's ability to continue as a going concern for at least the next twelve months from the financial reporting date.

Management believes that the current cash flow and support from the dental business will not be able to mitigate the expected selling expenditures for commercialization of the Epidural medical device, as well as other operating expenditures and planned new product development programs, over the next twelve months from the filing date of this quarterly report. Further, as a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of Covid-19, we anticipate that our revenue for the second quarter, and possibly the third quarter, will be materially and adversely affected. At this point in time, it is too early to determine an estimate of what the second or third quarter impact will be or the effect Covid-19 may have on our fourth quarter revenue. In addition, it is too early to determine what the effect will be on the anticipated commercialization of our Compuflow Epidural system as a medical device in 2020. Without additional funding a delay, scale back or elimination of some or all of the Company's medical commercial strategy or development programs could be required, all of which could have a material adverse impact on the Company. As a result of the extreme volatility in the financial markets due to the continuing spread of Covid-19, we may not be able to raise capital when needed or in sufficient amounts or execute strategic initiatives or transactions. Our inability to raise funds when and in the amounts required would have a material adverse effect on our business and financial condition.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in February 2019 (a capital raise in a public and private offering) provided Milestone Scientific with working capital to continue marketing of the CompuFlo Epidural System and to market its dental devices. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, and a reduction in operating expenses.

Now that the *CompuFlo* Epidural System has obtained FDA clearance in the United States (June 2017), the development costs will be reduced in 2020 but the selling costs are expected to increase significantly. The FDA clearance has provided the Company with the opportunity to establish distribution in the USA. At the same time, the Company is looking to establish additional financing to support the Epidural device commercialization process. The intra-articular device 510(k) application has been deferred until funding becomes available.

Milestone Scientific believes that the FDA clearance of its 510(k) application with respect to the *CompuFlo* Epidural System will provide Milestone Scientific with the opportunity to enter the US medical device market and generate revenues in the future. Milestone Scientific believes that it has sufficient inventory of the epidural devices to satisfy the near-term marketing opportunities.

Off-Balance Sheet Arrangements

Milestone Scientific does not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to the financial position or results of operations.

Contractual Obligations

The impact of the consolidated contractual obligations at December 31, 2019 , expected on the liquidity and cash flows in future periods, is as follows:

Payments Due by Period	Total	Less than 1 Year	1-3 Years	3-5 Years
Operating lease obligations	$ 638,025	$ 122,040	$ 252,428	$ 263,558
Purchase obligations (1)	$ 1,594,896	$ 1,594,896	$ -	$ -
Total	$ 2,232,921	$ 1,716,936	$ 252,428	$ 263,558

(1) Purchase obligations include agreements for the purchase of dental and medical devices.

Recent Accounting Pronouncements

See “Note C - Summary of Significant Accounting Policies” to the Consolidated financial statements for explanation of recent accounting pronouncements impacting Milestone Scientific.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Milestone Scientific is a “smaller reporting company” as defined by Regulation S-K and, as such, is not required to provide the information required by this item.

Item 8. Financial Statements

The financial statements of Milestone Scientific required by this Item are set forth beginning on page F-1.

Item 9. Change in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Milestone Scientific's Interim Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of Milestone Scientific's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based upon that evaluation, Milestone Scientific's Interim Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of December 31, 2019 are effective to ensure that information required to be disclosed in the reports Milestone Scientific files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Milestone Scientific's management, including the Interim Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Milestone Scientific management is responsible for establishing and maintaining internal controls over financial reporting. The internal controls over financial reporting includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles in the United States, and that the receipts and expenditures are being made only in accordance with authorizations of the management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control instruments, no matter how well designed, have inherent limitations. Therefore, even those instruments determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Milestone Scientific management assessed the effectiveness of its internal control over financial reporting as of December 31, 2019. In making this assessment, management used the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") adopted in 2013. Based on the assessment and the criteria set forth by COSO, management believes that Milestone Scientific maintained effective internal control over financial reporting as of December 31, 2019. There have been no changes in Milestone Scientific's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone Scientific's last fiscal quarter ended December 31, 2019 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, Promoters, Control Persons and CorporateGovernance; Compliance with Section 16 (a) of the Exchange Act.

Milestone Scientific's directors are elected annually by the stockholders and serve for one-year terms until his/her successor is elected and qualified or until such director's earlier death, resignation or removal. The executive officers and key personnel are appointed by and serve at the discretion of the Board of Directors The current executive officers and directors of Milestone Scientific and their respective ages as of March 30, 2019 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leslie Bernhard (1) (2) (3)	75	Chairman of the Board	2003
Leonard Osser	72	Interim Chief Executive Officer and Director	1991
Brent Johnston	50	President	
Joseph D'Agostino	68	Chief Financial Officer and Chief Operating Officer	
Leonard Schiller (1) (2) (3)	79	Director	1997
Gian Domenico Trombetta	59	Director	2014
Michael McGeehan (1) (2) (3)	54	Director	2017
Neal Goldman (2) (3)	76	Director	2019

1. Member of the Audit Committee
2. Member of the Compensation Committee
3. Member of the Nominating and Corporate Governance Committee

The following are the names of individuals who are not executive officers of Milestone Scientific but are deemed key personnel of Milestone Scientific, their respective ages and positions as of March 30, 2019 .

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	75	Director of International Professional Relations
Mark Hochman, D.D.S.	60	Director of Clinical Affairs

Leonard Osser, Interim Chief Executive Officer and Director

Leonard Osser has been Interim Chief Executive Officer since December 2017. From July 2017 to December 2017, he had been Managing Director –China Operations. Prior to that, he served as Milestone Scientific's Chairman from 1991 until September of 2009, and during that time, from 1991 until 2007, was also Chief Executive Officer of Milestone Scientific. In September 2009, he resigned as Chairman of Milestone Scientific, but remained director, and assumed the position of Chief Executive Officer. From 1980 until the consummation of Milestone Scientific's public offering in November 1995, Mr. Osser was primarily engaged as the principal owner and Chief Executive Officer of U.S. Asian Consulting Group, Inc., a New Jersey-based provider of consulting services specializing in distressed or turnaround situations in both the public and private markets. Mr. Osser's knowledge of our business and background with us since 1980 provides the Board with valuable leadership skills and insight into our business and accordingly, the expertise needed to serve as one of our directors.

Joseph D'Agostino, Chief Financial Officer and Chief Operating Officer

Joseph D'Agostino has been Milestone Scientific's Chief Financial Officer since October 2008 and Chief Operating Officer since September 2011. Mr. D'Agostino joined Milestone Scientific in January 2008 as Acting CFO and has over 25 years of finance and accounting experience serving both publicly and privately held companies. A results-oriented and decisive leader, he has specific proven expertise in treasury and cash management, strategic planning, information technology, internal controls, Sarbanes-Oxley compliance, operations and financial and tax accounting. Mr. D'Agostino served as Senior Vice President and Treasurer of Summit Global Logistics, a publicly traded, full service international freight forwarder and customs broker with operations in the United States and China.

Previous executive posts also included Executive Vice President and CFO of Haynes Security, Inc., a leading electronic and manned security solutions company serving government agencies and commercial enterprises; Executive Vice President of Finance and Administration for Casio, Inc., the U.S. subsidiary of Casio Computer Co., Ltd., a leading manufacturer of consumer electronics with subsidiaries throughout the world; and Manager of Accounting and Auditing for Main Hurdman's National Office in New York City (merged into KPMG). Mr. D'Agostino is a Certified Public Accountant and holds memberships in the American Institute of CPA's, New Jersey Society of CPA's, Financial Executive Institute, He is a graduate of William Paterson University where he earned a Bachelor of Arts degree in Science.

Leslie Bernhard, Chairman of the Board

Leslie Bernhard has served as Milestone Scientific's Chairman of the Board since October 2009 and served as Interim Chief Executive Officer from October 2017 to December 2017. In addition, Ms. Bernhard has also had been serving as an independent director of Milestone Scientific since May 2003. Since 2017, Ms. Bernhard has been an independent director of Sachem Capital Corp (NYSE American: SACH) a Connecticut based real-estate investment trust. From 2007, Ms. Bernhard served as an independent director of Universal Power Group, Inc., a global supplier of power solutions until it became a private company in 2018. In 1986 she co-founded AdStar, Inc., an electronic ad intake service to the newspaper industry, and served as its president, chief executive officer and executive director until 2012. Ms. Bernhard holds a BS Degree in Education from St. John's University. Ms. Bernhard's professional experience and background with AdStar and with us, as one of our directors since 2003, have given her the expertise needed to serve as Chairman of the Board, and Chairman of the Audit Committee.

Gian Domenico Trombetta, Director

Gian Domenico Trombetta has been a director of Milestone Scientific in May 2014 and the President and Chief Executive Officer of Milestone Scientific's Dental Division (Wand Dental Inc.) since October 2014. He founded Innovest S.p.A in 1993, a special situation firm acting in development and distressed capital investments. He has been its President and Chief Executive Officer since its inception. He served as the Chief Executive Officer or a board member of several private commercial companies in different industries including both industrial (e.g. IT, media, web, and fashion) and holding companies. Before founding Innovest, Mr. Trombetta was Project Manager for Booz Allen & Hamilton Inc., a management consulting firm from 1988 to 1992. Mr. Trombetta holds a degree in business administration from the Luiss University in Rome, Italy and an MBA degree from INSEAD-Fontainbleau-France. Mr. Trombetta business background and experience has given him the expertise needed to serve as one of our directors.

Leonard M. Schiller, Director

Leonard Schiller has been a director of Milestone Scientific since April 1997. Mr. Schiller has been a partner in the Chicago law firm of Schiller Strauss & Lavin PC since 1977 and since 2002, its President. Mr. Schiller also serves as a director on the boards of Jerrick Media Holdings, Inc., a public media company, since February 2016 and Point Capital, Inc., a business development company, since July 2014. Mr. Schiller's professional experience and background have given him the expertise needed to serve as Chairman of the Compensation Committee and as one of our directors.

Michael McGeehan

Michael McGeehan has been a director of Milestone Scientific since October 2017. Mr. McGeehan is a business consultant with 30 years of experience in a variety of business domains, including financial services, medical and healthcare products, consumer package goods and the software technology industry. Mr. McGeehan started his career at Metaphor Computer Systems in 1988 and then went to work at Microsoft Corporation in 1991. In 1995, Mr. McGeehan left Microsoft and founded Forefront Information Strategies, an information technology consulting firm. In 2002, Mr. McGeehan returned to Microsoft where he worked until 2017, when he returned to and re-started Forefront. Mr. McGeehan professional experience and background have given him the expertise needed to serve as Chairman of the Corporate Governance and Nominating Committee and as one of our directors.

Mr. McGeehan was on the Board of Directors of Wand Dental Inc., (subsidiary of Milestone Scientific) a maker of a painless, anesthetic injection system for dentists. Mr. McGeehan has a Master's in Business Administration from Pace University and a Bachelor of Science in Electrical Engineering and Computer Science from Marquette University. Mr. McGeehan background has given him the experience needed to serve as one of our directors.

Neal Goldman

Mr. Goldman is the President and Founder of Goldman Capital Management, Inc., a family office since 2018, which was previously an investment advisory firm founded in 1985. He was First Vice President of Research at Shearson Lehman Hutton. He has also held senior positions as a money manager and research analyst with a variety of firms including Neuberger Berman, Moseley Hallgarten Estabrook and Weeden, Bruns Nordeman, and Russ and Company. Mr. Goldman serves as Chairman of Charles & Colvard, Ltd. (Nasdaq: CTHR) since 2016 and serves on the board of Imageware Systems, Inc. (Nasdaq: IWSY). He also serves on the board of Deep-Down Inc. (DPDW). Prior to their acquisition, he served on the boards of Blyth Industries and IPASS Corporation. Mr. Goldman is a Chartered Financial Analyst (CFA). He also serves on numerous non-profit boards. Mr. Goldman received his B.A. degree in Economics from The City University of New York (City College).

Brent Johnston, President

Brent Johnston has been Milestone Scientific's President since September 2019. Mr. Johnston is a senior level, medical device industry executive with over 25 years of experience in sales, marketing and organizational efficiency. Prior to joining the Company, Mr. Johnston served as Vice President of Sales at Clariance, a spinal device company, since 2016. From 2015 until December 2016, Mr. Johnston served as Chief Executive Officer at ExsoMed, an upper extremity orthopedic company. Mr. Johnston founded and served as Chief Operating Officer at Aurora Spine, Inc., from 2011 until 2015. Mr. Johnston held senior executive roles at Phygen Spine (from 2009 until 2011) and Lanx, Inc. (from 2007 until 2009). Mr. Johnston also founded Corvus Medical, Inc., a company focused on products in spine, orthopedics, biologics and durable goods, in 2004. Mr. Johnston received a bachelor's degree in Political Science and Business Administration from Eastern Washington University and received a Master of Business Administration from Norwich University.

Mark Hochman, D.D.S., Director of Clinical Affairs

Mark Hochman, D.D.S. has served as Milestone Scientific's Director of Clinical Affairs and Director of Research and Development since 1999. He has a Doctor of Dental Surgery with advanced training in the specialties of Periodontics and Orthodontics from New York University of Dentistry and has been practicing dentistry since 1984. He is a former clinical associate professor at NYU School of Dental Surgery. Recognized as a world authority on Advanced Drug Delivery Instruments, Dr. Hochman has published numerous articles in this area, and shares in the responsibility for inventing much of the technology currently available from Milestone Scientific.

Dr. Eugene Casagrande, Director of International & Professional Relations

Since 1998, Eugene Casagrande, D.D.S. has served as Director of International and Professional Relations, charged with pursuing a broad range of clinical and industry-related strategic business opportunities for Milestone Scientific. Dr. Eugene R. Casagrande has practiced Cosmetic and Restorative Dentistry for over 30 years in Los Angeles. He is past president of the California State Board of Dentistry and the Los Angeles Dental Society and is a Fellow of the American and International Colleges of Dentists. Dr. Casagrande was a member of the faculty of the University of Southern California, School of Dentistry. He was also the Executive Director of the Los Angeles Oral Health Foundation and the Program Director of the Los Angeles Pediatric Oral Health Access Program. As the Director of International & Professional Relations for Milestone Scientific for over 20 years, he has published multiple articles and has lectured both nationally and internationally at over 100 dental schools and in over 50 countries on Computer-Controlled Local Anesthesia.

Director Independence and Committees of the Board

The Board has determined that Leslie Bernhard, Leonard M. Schiller, Neal Goldman, and Michael McGeehan (the "Independent Directors") are independent as that term is defined in the listing standards of the NYSE American. As disclosed above, Leslie Bernhard, Leonard M. Schiller, and Michael McGeehan are members of the Audit Committee and are independent for such purposes. Leslie Bernhard, Leonard M. Schiller, and Neal Goldman, are members of the Compensation Committee and are independent for such purposes.

Milestone Scientific's Board of Directors has established a compensation, audit, nominating and corporate governance committees (respectively, "Compensation Committee," "Audit Committee," and "Nominating Committee".) The Compensation Committee reviews and recommends to the Board of Directors the compensation and benefits of all the officers of Milestone Scientific, reviews general policy matters relating to compensation and benefits of employees of Milestone Scientific and administers the issuance of stock options to Milestone Scientific's officers, employees, directors and consultants. All compensation arrangements between Milestone Scientific and its directors, officers and affiliates are reviewed by the Compensation Committee.

The Audit Committee meets with management and Milestone Scientific's independent auditors to determine the adequacy of internal controls and other financial reporting matters; all the members are independent directors. The Board of Directors has determined that, Leslie Bernhard qualifies as an Audit Committee Financial Expert pursuant to Item 407(d)(5) of Regulation S-K, Leslie Bernhard is independent, as that term is defined in the listing standards of the NYSE American.

The Nominating Committee has dual responsibilities. The Nominating Committee will assist the board by identifying and recommending individuals qualified to become member of the board. Additionally, the committee will evaluate the size and composition of the board and its members, reviewing governance issues and making recommendations to the board regarding possible changes and reviewing and monitoring compliance with the code of ethics and insider trading policy.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Executive officers, directors and greater than ten-percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. Based solely on review of the copies of such forms furnished to us, or written representations that no Forms 5 were required, we believe that all Section 16(a) filing requirements applicable to our officers and director were complied with during the fiscal year ended December 31, 2019.

Code of Ethics

Milestone Scientific has adopted a code of ethics that applies to its directors, principal executive officer, principal financial officer and other persons performing similar functions. This code of ethics is posted on Milestone Scientific's web site at www.milestonescientific.com. Milestone Scientific will also provide a copy of the Code of Ethics to any person without charge, upon written request addressed to the Chief Financial Officer, Joseph D'Agostino at the principal executive office, located at 425 Eagle Rock road Roseland, NJ 07068.

Item 11. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2019 and 2018 by Milestone Scientific's (i) Interim CEO and (ii) two most highly compensated executive officers other than the Interim CEO who were serving as executive officers at the end of the 2019 fiscal year and whose salary as determined by Regulation S-K, Item 402, exceeded $100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the "Named Executive Officers").

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary	Bonuses	Option Awards	Other Compensation	Total
Leonard A. Osser (1)						
Interim Chief Executive Officer	2019	$ 301,423	$ 350,000	$ -	$ 39,879	$ 691,302
	2018	$ 304,167	$ -	$ -	$ 236,317	$ 540,484
Gian Domenico Trombetta (2)						
Chief Executive Officer - Wand Dental Inc	2019	$ 280,000	$ -	$ -	$ -	$ 280,000
	2018	$ 280,000	$ -	$ -	$ -	$ 280,000
Joseph D'Agostino (3)						
Chief Financial Officer and Chief Operating Officer	2019	$ 203,300	$ 175,000	$ -	$ 24,935	$ 403,235
	2018	$ 200,000	$ -	$ -	$ 25,298	$ 225,298
Brent Johnston (4)						
President	2019	$ 86,218	$ 16,666	$ -	$ 9,033	$ 111,917
Sharon Smith (5)						
Executive Vice President Global Marketing	2019	$ 181,064			$ -	$ 181,064
	2018	$ 167,535	$ 116,500	$ -	$ -	$ 284,035
Eric Gilbert (6)						
Vice President US Sales and Marketing	2019	$ 218,301				$ 218,301
	2018	$ 155,242	$ 70,000	$ -	$ -	$ 225,242

1. Leonard Osser deferred a portion of his yearly compensation of approximately $175,000 in 2019 and 2018, respectively. During 2019 other compensation represents payments made for health insurance coverage of approximately $25,000 and car allowance of approximately $14,400 in 2019. In 2018, Mr. Osser, deferred his pension of approximately $203,111 which was included in other payments. In 2019, Mr. Osser received $60,000 of the deferred pension from 2018. Mr. Osser received a discretionary performance bonus in 2019 of $350,000 (which will be paid stock) and no bonus was award for 2018 respectively. During 2018, other compensation represents payments made for health insurance coverage $19,000 and car allowance $14,400, pension payment $203,111.

2. Gian Domenico Trombetta deferred a portion of his yearly compensation of approximately $180,000 in 2019 and 2018, respectively. Mr. Trombetta did not receive a performance bonus in 2019 and 2018.

3. Joseph D'Agostino deferred a portion of his yearly compensation of approximately $28,400 in 2019 and 2018. During 2019 other compensation represents payments made for health insurance coverage of approximately $16,000 and car allowance of approximately $9,000. Mr. D'Agostino received a discretionary performance bonus in 2019 of $175,000 (which will be paid stock) and no bonus was awarded in 2018. During 2018 other compensation represents payments made for health insurance coverage of approximately $16,000 and car allowance of approximately $9,000.

4. Brent Johnston was hired in September 2019 as President. His yearly compensation was approximately $86,000 in 2019. Other compensation represents payments made for health insurance coverage of approximately $4,800 and car allowance of approximately $4,200. Mr. Johnston received a discretionary performance bonus in 2019 of approximately $16,000.

5. Sharon Smith received $116,500, in a discretionary performance bonus for the year ended December 31, 2018, which was paid in common stock upon her termination with the Company in October 2019.

6. Eric Gilbert received $70,000, in a discretionary performance bonus for the year ended December 31, 2018, and will be paid in common stock upon the termination of his employment with the Company.

Employment Contracts

In July 2017, Milestone Scientific entered into a ten-year employment agreement with Leonard Osser, who previously served as the Company's President and Chief Executive Officer, to serve as Managing Director – China Operations. This agreement provides for annual compensation of $300,000 consisting of $100,000 in cash and $200,000 in the Company's common stock valued at the average closing price of the Company's common stock on the NYSE or such other market or exchange on which its shares are then traded during the first fifteen (15) trading days of the last full calendar month of each year during the term of this agreement. This agreement supersedes all prior employment agreements between Mr. Osser and Milestone Scientific. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term.

In July 2017, Mr. Osser also resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive $100,000 per year for Mr. Osser's services.

On December 19, 2017 the Board of Directors appointed Leonard Osser Interim Chief Executive Office, replacing Leslie Bernhard. Mr. Osser placed on hold his position as Managing Director-China Operations and his consulting agreement with Milestone Medical to rejoined Milestone Scientific Inc. as Interim Chief Executive Officer and will not receive or earn any compensation under those agreements until he is no longer Interim Chief Executive Officer. Mr. Osser as Interim Chief Executive Officer receives a base salary and may receive bonus determined by the compensation committee of Company.

Objective of Executive Compensation Program

The primary objective of the executive compensation program is to attract and retain qualified, energetic managers who are enthusiastic about the mission and culture of Milestone Scientific. A further objective of the compensation program is to provide incentives and reward each manager for their contribution. In addition, Milestone Scientific strives to promote an ownership mentality among key leadership and the Board of Directors.

The Compensation Committee reviews and approves, or in some cases recommends for the approval of the full Board of Directors, the annual compensation procedures for the Named Executive Officers.

The compensation program is designed to reward teamwork, as well as each manager's individual contribution. In measuring the Named Executive Officers' contribution, the Compensation Committee considers numerous factors including the growth, strategic business relationships and financial performance. Regarding most compensation matters, including executive and director compensation, management provides recommendations to the Compensation Committee; however, the Compensation Committee does not delegate any of its functions to others in setting compensation. Milestone Scientific does not currently engage any consultant to advise on executive and/or director compensation matters.

Stock price performance has not been a factor in determining annual compensation because the price of Milestone Scientific's common stock is subject to a variety of factors outside of Milestone Scientific's control. Milestone Scientific does not have an exact formula for allocating between cash and non-cash compensation.

Annual CEO Compensation consists of a base salary component and periodic stock option grants. It is the Compensation Committee's intention to set totals for the CEO for cash compensation sufficiently high enough to attract and retain a strong motivated leadership team, but not so high that it creates a negative perception with the other stakeholders. The CEO receives stock option grants under the stock option plan. The number of stock options granted to the executive officer is made on a discretionary rather than a formula basis by the Compensation Committee.

The CEO's current and prior compensation is considered in setting future compensation. To some extent, the compensation plan is based on the market and the companies that compete for executive management. The elements of the plan (e.g., base salary, bonus and stock options) are like the elements used by many companies. The exact base pay, stock option grant, and bonus amounts are chosen to balance the competing objectives of fairness to all stakeholders and attracting and retaining executive managers.

Outstanding Equity Awards at December 31, 2019

	Options Awards				**Stock Awards**	
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable (1)**	**Number of Securities Underlying Unexercised Options (#) Unexercisable (1)**	**Option Exercise Price ($)**	**Option Expiration Date**	**Number of Shares or Units of Stock that have not vested (#) (2)**	**Market Value of Number of Shares or Units of Stock that have not vested (#) (3)**
Leonard Osser	57,306	-	$ 3.56	6/23/2020	1,241,303	$ 1,725,411
	82,988	-	$ 1.72	2/4/2021		
	171,429	-	$ 1.93	11/10/2021		
	62,112	-	$ 1.71	2/4/2021		
	261,713	75,257	$ 1.14	12/31/2021		
Total	**635,548**	**75,257**			**1,241,303**	$ **1,725,411**
Gian Domenico Trombetta	132,780	-	$ 1.72	2/4/2021	202,617	281,638
	99,378	-	$ 1.61	1/8/2022		
Total	**232,158**	**-**			**202,617**	**281,638**
Brent Johnston	-	-	$ -	-	13,117	$ 18,233
	-	-	$ -	-		
Total	**-**	**-**			**13,117**	$ **18,233**
Joseph D'Agostino	133,140	-	$ 1.72	2/4/2021	313,860	$ 436,265
	49,689	-	$ 1.61	12/31/2021		
	67,298	19,352	$ 1.04	12/31/2021		
Total	**250,127**	**19,352**			**313,860**	**$ 436,265**

The following table includes certain information with respect to all unexercised stock options and unvested shares of common stock of Milestone Scientific outstanding owned by the Named Executive Officers at December 31, 2019.

1. Represents stock option grants at fair market value on the date of grant.
2. Issuance of the shares of common stock have been deferred until the termination of employment with Milestone Scientific in accordance with the terms of respective employment arrangements.
3. Based on the closing price per share of $1.39 as reported on the NYSE American on December 31, 2019.

Director Compensation

The following table shows the compensation earned by or awarded or paid in 2019 to the individuals who served as our non-employee directors during such period. Neither Mr. Osser nor Mr. Trombetta received any additional compensation for their services as a director.

NAME	Fees Earned or Paid in Cash ($)	Fees Earned or Paid in Common Stock
Leslie Bernhard	$ 66,000	-
Leonard Schiller	$ 16,000	20,000
Dr. Edward Zelnick	$ 16,000	20,000
Michael McGeehan	$ -	36,000
Neal Goldman	$ -	36,000

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table, together with the accompanying footnotes, sets forth information, as of March 27, 2020 , regarding stock ownership of all persons known by Milestone Scientific to own beneficially more than 5% of Milestone Scientific's outstanding common stock, Named Executives, all directors, and all directors and officers of Milestone Scientific as a group:

Names of Beneficial Owner (1)	Shares of Common Stock Beneficially Owned (2)		Percentage of Ownership
Executive Officers and Directors			
Leonard Osser	4,516,807	(3)	8.66%
Brent Johnston	13,117	(4)	*
Joseph D'Agostino	1,495,124	(5)	2.87
Leslie Bernhard	75,000	(6)	*
Leonard Schiller	265,660	(7)	*
Michael McGeehan	154,929	(8)	*
Neal Goldman	1,358,862	(9)	2.61%
Gian Domenico Trombetta	10,310,538	(10)	19.77%
All directors & executive officers as group (8 persons)	18,190,037		33.91%
K. Tucker Andersen	3,669,87		7.04%
Tom Cheng	1,998,313		3.83%

1. The addresses of the persons named in this table are as follows: Leonard Osser, Joseph D'Agostino, Gian Domenico Trombetta, Leslie Bernhard, Edward Zelnick, M.D and Michael McGeehan are at 425 Eagle Rock Avenue, Roseland, New Jersey 07068; Leonard M. Schiller, c/o Schiller, Klein & McElroy, P.C., 33 North Dearborn Street, Suite 1030, Chicago, Illinois 60602; K. Tucker Andersen, c/o Above All Advisers, 61 Above All Road, Warren, CT 06754, and Tom Cheng, c/o United Systems 18725 E. Gale Ave Suite 221, City of Industry, CA 91748.

2. A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 27, 2020, as applicable, upon the exercise of options and warrants or conversion of convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants and convertible securities that are held by such person (but not held by any other person) and that are exercisable or convertible within 60 days from March 27, 2020 have been exercised or converted. Except as otherwise indicated, and subject to applicable community property and similar laws, each of the persons named has sole voting and investment power with respect to the shares shown as beneficially owned. The percentages for each beneficial owner are determined based on dividing the number of shares of common stock beneficially owned by the sum of the outstanding shares of common stock on March 27, 2020 and the number of shares underlying options exercisable and convertible securities convertible within 60 days from March 27, 2020 held by the beneficial owner

3. Includes 2,568,706 shares held by Mr. Osser or his family, 1,241,303 shares to be issued at the termination of his employment agreement, and 635,548 shares subject to common stock options and 71,250 shares subject to warrants to purchase common stock of the company.

4. Includes 13,117 shares to be issued at the termination of his employment.

5. Includes 931,137 shares held by Mr. D'Agostino, 313,860 shares to be issued at the termination of his employment, and 250,127 shares subject to common stock options.

6. Includes 75,000 shares held by Ms. Bernhard.

7. Includes 265,660 shares held by Mr. Schiller and 5,625 shares subject to common stock warrants to purchase common stock of the Company.

8. Includes 154.929 shares held by Mr. McGeehan and 21,250 shares subject to common stock warrants.

9. Includes 1,216,362 shares held by Mr. Goldman and 142,500 shares subject to common stock warrants.

10. Includes 202,617 shares to be issued at the termination of his employment, 232,158 shares subject to common stock options, 178,571 shares subject to warrants to purchase common stock of the Company in the name of Bp4 Sr.l, and 9,697,192 shares held directly by BP4 S.r.l. ("BP4") of which 5,982,906 shares were issued upon the conversion of $7 million of preferred stock at $1.17 per share, as adjusted to date. Innovest S.p.A. ("Innovest") is the controlling shareholder of BP4 and Mr. Trombetta is a controlling shareholder and director of Innovest, and, as such, is deemed to have voting and investment power over the securities held by BP4. Mr. Trombetta disclaims beneficial ownership of all securities held by BP4.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes, as of December 31, 2019, the (i) options granted under the Milestone Scientific 2004 Stock Option Plan (the “2004 Plan”) and (ii) options granted under the Milestone Scientific 2011 Equity Compensation Plan (f/k/a Milestone Scientific 2011 Stock Option Plan) (the “2011 Plan”). The shares covered by outstanding options and warrants are subject to adjustment for changes in capitalization, stock splits, stock dividends and similar events. No other equity compensation has been issued.

Equity compensation plan approved by stockholders	Number of Securities to be issued upon exercise of outstanding options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance under equity compensation plan
Grants under our 2004 Stock Option Plan (1)	-	-	-
Grants under our 2011 Stock Option Plan (2)	1,262,440	$ 1.64	652,044
Total	1,262,440	1.64	652,044

1. The 2004 Plan, as amended, provided for awards of options up to a maximum 750,000 shares of Milestone Scientific's common stock and expired in July 2014. Options were granted to employees, officers, directors and consultants of Milestone Scientific for the purchase of common stock of Milestone Scientific at a price not less than the fair market value of the common stock on the date of the grant. In general, options awarded under the 2004 Plan became exercisable over a three-year period from the grant date and expire five years after the date of grant. No options were exercised in 2019 or 2018. The options expired in 2019.

2. The 2011 Plan, as amended, provides for awards of restricted common stock and options to purchase up to a maximum 4,000,000 shares of common stock and expires in June 2021. Options may be granted to employees, directors and consultants of Milestone Scientific for the purchase of shares of common stock at a price not less than the fair market value of common stock on the date of grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. For the years ended December 31, 2019 and 2018, zero were exercised.

Item 13. Certain Relationships and Related Transactions and Director Independence.

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were $1.2 million for the years ended December 31, 2019 and 2018. As December 31, 2019 and 2018, Milestone Scientific owed this manufacturer approximately $943,000 and $1.3 million, respectively, which is included in accounts payable, related party on the consolidated balance sheets. In February 2019, Milestone Scientific board of directors granted United Systems 285,714 shares of stock at $0.35 or $100,000 for consulting services. These shares were issued in July 2019.

During 2018, Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of December 31, 2019, Wand Dental has deferred royalty income of $342,500 that will be recognized at the earlier of when payment of the royalties is received from United Systems or when collectability is deemed to be assured and is included in accounts receivable, related party and deferred revenue, related party on the consolidated balance sheets. This receivable is included in the reserved receivables in Note F.

Also, during the year ended December 31, 2018, a Distribution Agreement between Wand Dental and United Systems was formed. Under the Distribution Agreement United Systems purchased 1,000 STA instruments in June 2018, for delivery to Milestone China. Due to the related party nature and collectability concerns Wand Dental has deferred the sale. Milestone Scientific has deferred approximately $750,000 of related party sales of devices to Milestone China under the agreement with United Systems as of December 31, 2018. As of December 31, 2019, Milestone Scientific recorded accounts receivable, related party and deferred revenue, related party of $750,000 and deferred cost, related of $686,365, respectively. The deferred revenue, accounts receivable and deferred cost from this transaction are included in accounts receivable, deferred revenue and deferred cost related, party related to Milestone China disclosed on the consolidated balance sheets. This receivable, deferred revenue and deferred cost is included in the reserved receivables in Note F.

In June 2014, Milestone Scientific invested $1 million in Milestone China by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting. Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and it’s agents which amounted to $ 2.8 million at the time of the payment arrangement. The payment terms required payments of $200,000 per month beginning in July 2018 through November 2018 and a balloon payment of approximately $1,425,000 during December 2018. Due to the default on the arrangement and Milestone China’s liquidity constraints, Milestone Scientific halted shipments to Milestone China. The Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a reserve against the related deferred cost of $1.25 million which includes the sales to United Systems. The amounts due from United Systems described above are included in the adjustments and reserves for Milestone China. See note F for a description of related party transactions with Milestone China.

In July 2019, United System issued a credit to the Company for approximately $151,000 for handpieces found to be defective. The Company recorded the credit in cost of sales since the Company previously
recorded an allowance for against inventory during 2018.

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were $100,000 for years ended December 31, 2019 and 2018, respectively. In December 2019, Milestone Scientific extended this agreement for one year at a cost of $100,000.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific, to provide consulting services. This agreement will renew for successive twelve-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were $80,000 for years ended December 31, 2019 and 2018, respectively.

The Director of Clinical Affairs' royalty fee was approximately $403,000 and $465,000 for the years ended December 31, 2019 and 2018, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $156,000 and $186,000 for the years ended December 31, 2019, and 2018, respectively. As of December 31, 2019 and 2018 Milestone Scientific owed the Director Clinical Affairs for royalties of approximately $390,000 and $364,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

Item 14. Principal Accounting Fees and Services

Audit Fees and Audit Related

Milestone Scientific incurred audit and financial statement review fees of approximately $252,000 and $246,500, respectively from Friedman LLP, its principal accountant for 2019 and 2018. These fees include fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Q's or services that are normally provided in connection with statutory and regulatory filings and fees related to registration statements.

Tax Fees

Milestone Scientific incurred tax fees of approximately $36,000 and $42,500 respectively from Friedman LLP, its principal accountant for 2019 and 2018.

All Other Fees

Milestone Scientific incurred other accounting fees of approximately $0 and $50,000 from Friedman LLP, its principal accountant in both 2019 and 2018, respectively.

Audit Committee Administration of the Engagement

The engagement with Friedman LLP, the principal accountants, was approved in advance by the Board of Directors and the Audit Committee. No non-audit or non-audit related services were approved by the Audit Committee in 2019.

Audit Committee Pre-Approval Policies and Procedures

The Audit Committee charter provides that the Audit Committee will pre-approve audit services and non-audit services to be provided by the independent auditors before the accountant is engaged to render these services. The Audit Committee may consult with management in the decision-making process but may not delegate this authority to management. The Audit Committee may delegate its authority to preapprove services to one or more committee members, provided that the designees present the pre-approvals to the full committee at the next committee meeting. All audit and non-audit services performed by the independent accountants have been pre-approved by the Audit Committee to assure that such services do not impair the auditors' independence from us.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Report:

1 Financial Statements. See Index to Financial Statements on page F-1.

2 Financial Statement Schedule
Schedules are omitted because the information required is not applicable or the required information is shown in the consolidated financial statements or notes thereto.

3 Exhibits
Certain of the following exhibits were filed as Exhibits to previous filings filed by Milestone Scientific under the Securities Act of 1933, as amended, or reports filed under the Securities and Exchange Act of 1934, as amended, and are hereby incorporated by reference.

Exhibit No	Description
3.1	Restated Certificate of Incorporation of Milestone filed on September 6, 2013 (11)
3.2	Form of Certificate of Designation filed on April 18, 2014 (12)
3.3	Certificate of Correction to the Certificate of Designation filed on May 12, 2014 (13)
3.4	Amended and Restated By-laws of Milestone filed April 1, 2019 (23)
4.1	Specimen stock certificate (2)
4.3	Form of Common Stock Purchase Warrant issued in the 2016 Public Offering (16)
4.4	Form of Common Stock Purchase Warrant issued in the Feb. 2019 Public Offering (21)
4.5	Form of Common Stock Purchase Warrant issued in the Feb. 2019 Private Placement (22)
10.1	Lease dated November 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (3)
10.2	Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (4)
10.3	2011 Equity Compensation Plan (7)
10.4	Master Supply and Distribution Agreement, dated July 3, 2013, between Milestone Scientific Inc and Tri-anim Health Services, Inc (9)
10.5	Agreement with Mark Hochman, dated July 2015 (13)
10.6	Investment Agreement, dated April 15, 2014, between Milestone Scientific Inc. and BP4 S.p.A. (12)
10.7	Exclusive Distribution and Supply Agreement, dated as of June 20, 2016, among Milestone Scientific Inc., Wand Dental, Inc. and Henry Schein, Inc. (14)
10.8	Amended and Restated Employment Agreement, dated December 1, 2016, between Wand Dental Inc. and Gian Domenico Trombetta (15)
10.9	Final Form of Asset Purchase Agreement, dated June 2, 2017, among APAD Octrooi B.V., APAD B.V., and Milestone Scientific Inc. (17)
10.10	Final form of the Memorandum of Agreement, dated June 6, 2017, between Solee Science & Technology U.S.A. Ltd. and Milestone Scientific Inc. (18)
10.11	Final form of the Promissory Note, dated June 6, 2017, in the principal amount of $1,275,000 made by Solee Science & Technology U.S.A. Ltd. to Milestone Scientific Ltd. (18)
10.12	Final form of the Stock Option Agreement, dated June 6, 2017, Solee Science & Technology U.S.A. Ltd. and Milestone Scientific Inc. (18)
10.13	New Employment Agreement between Milestone Scientific Inc. and Leonard Osser dated as of July 11, 2017. (19)
10.14	Employment Agreement between Milestone Scientific Inc. and Daniel Goldberger dated as of July 11, 2017. (19)
10.15	Covenant Agreement between Milestone Scientific Inc. and Daniel Goldberger dated and effective as of July 11, 2017. (19)
10.16	Consultant Agreement between Milestone Medical Inc. and U.S. Asian Consulting Group, LLC dated as of July 10, 2017. (20)
10.17	Underwriting Agreement, dated as of February 1, 2019 between Milestone Scientific Inc. and Maxim Group LLC, as underwriter (21)
10.18	Stock Purchase Agreement, dated as of February 8, 2019 between Milestone Scientific Inc. and BP4 S.p.A. (22)
21.1	List of Subsidiaries*
23.1	Consent of Friedman, LLP*

31.1	Rule 13a-14(a) Certification-Chief Executive Officer*
31.2	Rule 13a-14(a) Certification-Chief Financial Officer*
32.1	Section 1350 Certifications-Chief Executive Officer***
32.2	Section 1350 Certifications-Chief Financial Officer***
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*

* Filed herewith.

** Indicates management contract or compensatory plan or arrangement.

*** Furnished, not filed, in accordance with item 601(32) (ii) of Regulations-S-K.

2) Incorporated by reference to Amendment No. 1 to Milestone Scientific's Registration Statement on Form 10-KSB for the year ended May 15, 1995
3) Incorporated by reference to Milestone Scientific's Form 10-KSB for the year ended December 31, 1996.
4) Incorporated by reference to Milestone Scientific's Form 10-KSB for the year ended December 31, 2004.
7) Filed as Appendix A to Milestone Scientific's Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.
9) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on July 9, 2013.
11) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2013.
12) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on April 18, 2014.
13) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2015.
14) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on June 30, 2016.
15) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on December 2, 2016.
16) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on December 16, 2016.
17) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on June 2, 2017.
18) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on June 7, 2017.
19) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on July 10, 2017.
20) Incorporated by reference to Milestone Scientific's Form 10-Q filed with the SEC on August 14, 2017.
21) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on February 1, 2019.
22) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on February 14, 2019.
23) Incorporated by reference to Milestone Scientific's Form 10-K filed with the SEC on April 1, 2019.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Milestone Scientific Inc.
By: /s/ Leonard Osser
Interim Chief Executive Officer
(Principal Executive Officer)

Date: March 30, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Date	Title
/s/ Leonard Osser Leonard Osser	March 30, 2020	Interim Chief Executive Officer (Principal Executive Officer)
/s/ Joseph D'Agostino Joseph D'Agostino	March 30, 2020	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)
/s/ Leslie Bernhard Leslie Bernhard	March 30, 2020	Chairman and Director
/s/ Gian Domenico Trombetta Gian Domenico Trombetta	March 30, 2020	Director
/s/ Leonard Schiller Leonard Schiller	March 30, 2020	Director
/s/ Michael McGeehan Michael McGeehan	March 30, 2020	Director
/s/ Neal Goldman Neal Goldman	March 30, 2020	Director

REPORT INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

For the Years Ended December 31, 2019 and 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Milestone Scientific, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Milestone Scientific, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, statements of changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B to the consolidated financial statements, the Company has recurring losses and negative cash flows from operations. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Friedman LLP
We have served as the Company's auditor since 2016.

East Hanover, New Jersey
March 30, 2020

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,516,272	$ 743,429
Accounts receivable, net	1,710,665	1,978,456
Accounts receivable, related party, net	-	100,000
Prepaid expenses and other current assets	519,063	414,541
Deferred cost, related party	-	50,000
Inventories, net	1,620,509	1,921,051
Advances on contracts	710,662	648,783
Operating lease-right of use assets	15,977	-
Total current assets	6,093,148	5,856,260
Furniture, fixtures and equipment, net	44,976	82,557
Patents, net	382,260	435,273
Other assets	35,905	26,878
Total assets	$ 6,556,289	$ 6,400,968
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,379,425	$ 1,059,186
Accounts payable, related party	1,358,752	1,810,058
Accrued expenses and other payables	775,055	794,918
Accrued expenses, related party	1,057,957	686,798
Operating lease liabilities	15,977	-
Deferred profit, related party	340,476	421,800
Deferred revenue, related party	-	100,000
Total current liabilities	4,927,642	4,872,760
Total liabilities	$ 4,927,642	$ 4,872,760
Commitments and contingencies		
Stockholders' equity		
Series A convertible preferred stock, par value $.001, authorized 5,000,000 shares, 0 and 7,000 shares issued and outstanding as of December 31, 2019 and 2018.	$ -	$ 7
Common stock, par value $.001; authorized 75,000,000 shares; 49,410,176 shares issued and 49,376,843 shares outstanding as of December 31,2019; 33,859,034 shares issued, 2,470,566 shares to be issued, and 33,825,701 shares outstanding as of December 31, 2018;	49,410	36,330
Additional paid in capital	96,082,324	88,414,718
Accumulated deficit	(93,524,297)	(85,999,929)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	1,695,921	1,539,610
Noncontrolling interest	(67,274)	(11,402)
Total stockholders' equity	$ 1,628,647	$ 1,528,208
Total liabilities and stockholders' equity	$ 6,556,289	$ 6,400,968

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2019 AND 2018

	2019	2018
Product sales, net	$ 8,374,501	$ 9,622,076
Cost of products sold	2,656,142	5,190,775
Gross profit	5,718,359	4,431,301
Selling, general and administrative expenses	9,527,429	10,645,206
Research and development expenses	189,923	245,636
Impairment of long -lived assets	-	1,539,794
Total operating expenses	9,717,352	12,430,636
Loss from operations	(3,998,993)	(7,999,335)
Other expenses	(10,408)	(7,232)
Interest income	1,543	7,447
Change in fair value of derivative liabilities	(3,635,580)	-
Loss before provision for income taxes and net of equity investments	(7,643,438)	(7,999,120)
Provision for income taxes	(18,126)	(23,986)
Loss before equity in net earnings of equity investments	(7,661,564)	(8,023,106)
Earnings from Milestone Education	-	(1,635)
Earnings from Milestone China	(81,324)	(329,700)
Net loss	(7,580,240)	(7,691,771)
Net loss attributable to noncontrolling interests	55,872	260,126
Net loss attributable to Milestone Scientific Inc.	(7,524,368)	(7,431,645)
Net loss per share applicable to common stockholders—		
Basic	$ (0.16)	$ (0.21)
Diluted	$ (0.16)	$ (0.21)
Weighted average shares outstanding and to be issued—		
Basic	45,740,050	35,299,034
Diluted	45,740,050	35,299,034

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2019 AND 2018

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, January 1, 2018	7,000	$ 7	34,592,818	$ 34,593	$ 86,689,084	$ (78,568,284)	$ 256,744	$ (911,516)	$ 7,500,628
Stock based compensation	-	-			409,021	-	-	-	409,021
Common stock issued to employee for bonuses		-	25,000	25	29,475				29,500
Common stock issued for payment of consulting services		-	350,102	350	289,400	-	-	-	289,750
Common stock issued to employee for compensation		-	47,402	47	44,953	-	-	-	45,000
Common stock issued for Asset Acquisition		-	244,959	245	286,357	-	-	-	286,602
Common stock to be issued to employee for bonuses		-	511,155	511	449,488	-	-	-	449,999
Common stock to be issued for payment of consulting services		-	535,437	536	209,463	-	-	-	209,999
Common stock to be issued to employee for compensation		-	22,727	23	7,477	-	-	-	7,500
Acquired controlling interest in Milestone Education		-	-	-	-	-	(8,020)	-	(8,020)
Net loss		-		-	-	(7,431,645)	(260,126)	-	(7,691,771)
Balance as December 31, 2018	7,000	$ 7	36,329,600	$ 36,330	$ 88,414,718	$ (85,999,929)	$ (11,402)	$ (911,516)	$ 1,528,208
Stock Compensation					183,888	-	-	-	183,888
Conversion of Preferred Shares to Common Stock	(7,000)	(7)	5,982,906	5,983	(5,976)	-	-	-	-
Common stock issued for warrants exercised	-	-	675,000	675	336,825	-	-	-	337,500
Common stock issued in private offering	-	-	714,286	714	249,286	-	-	-	250,000
Common stock issued in public offering	-	-	6,282,400	6,282	1,968,265	-	-	-	1,974,547
Common stock to be issued for bonus and compensation	-	-	428,635	429	790,237	-	-	-	790,666
Common stock to be issued for payment of consulting services			607,784	608	292,792				293,400
Common stock to be issued to Board of Directors			147,438	147	66,997				67,144
Common stock issued for payment of consulting services			339,058	339	147,616				147,955
Reclassification to derivative liability for securities issued in excess of shares authorized			(3,360,830)	(3,361)	(2,199,664)				(2,203,025)
Reversal of derivative liability for exercise of Warrants					655,000				655,000
Reversal of derivative liability for the issuance of shares-to-be-issued			1,263,899	1,264	1,066,562				1,067,826
Reversal of derivative liability to equity upon authorized share increase					4,115,778				4,115,778
Net Loss						(7,524,368)	(55,872)		(7,580,240)
	-	$ -	49,410,176	$ 49,410	$ 96,082,324	$ (93,524,297)	$ (67,274)	$ (911,516)	$ 1,628,647

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2019 AND 2018

	2019	2018
Cash flows from operating activities:		
Net loss	$ (7,580,240)	$ (7,691,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	47,495	66,604
Amortization of patents	53,013	814,681
Impairment to long lived assets	-	1,539,794
Stock compensation	183,888	409,021
Loss from earnings on China joint venture	(81,324)	(329,700)
Inventory reserve	-	543,545
Deferred cost reserve	-	1,250,928
Change in fair value of derivative liability	3,635,580	-
Amortization of right-of-use assets	155,962	-
Changes in operating assets and liabilities:		
Decrease (Increase) in accounts receivable	267,791	(442,943)
Decrease (Increase) in accounts receivable, related party	100,000	(192,540)
(Increase) in other receivables	(9,027)	-
Decrease in inventories	300,542	914,613
(Increase) Decrease in advances on contracts	(61,879)	48,409
(Increase) Decrease in prepaid expenses and other current assets	(104,522)	21,869
Increase in accounts payable	320,239	227,773
(Decrease) Increase in accounts payable, related party	(303,346)	678,171
Decrease (Increase) in deferred cost, related party	50,000	(191,257)
Increase in accrued expenses	273,537	620,797
Increase (Decrease) in accrued expenses, related party	1,228,965	(108,640)
Decrease in operating lease liability	(155,962)	-
(Decrease) Increase in deferred revenue, related party	(100,000)	192,540
Net cash used in operating activities	(1,779,288)	(1,628,106)
Cash flows from investing activities:		
Purchase of intangible assets	-	-
Purchase of property and equipment	(9,916)	(7,401)
Acquisition of Milestone Education	-	(8,020)
Net cash used in investing activities	(9,916)	(15,421)
Cash flows from financing activities:		
Payments for financing transaction	-	(250,000)
Proceeds from exercise of warrants	337,500	-
Net proceeds from Public Placement Offering	1,974,547	-
Net proceeds from Private Placement Offering	250,000	-
Net cash provided by financing activities	2,562,047	(250,000)
Net increase (decrease) in cash and cash equivalents	772,843	(1,893,527)
Cash and cash equivalents at beginning of period	743,429	2,636,956
Cash and cash equivalents at end of period	$ 1,516,272	$ 743,429
Supplemental non-cash disclosure of cash flow information:		
Shares issued to employee for bonuses	$ 753,000	$ -
Shares issued to board of directors for services rendered	$ 67,000	$ -
Shares issued to employees for compensation	$ 37,500	$ 45,000
Shares issued to consultants in lieu of cash payments	$ 440,400	$ 289,750
Sale of Milestone China share, financing transaction	$ -	$ (1,400,000)
Credit from United Systems for defective handpieces	$ (151,562)	$ -
Initial recognition of operating lease-right of use assets	$ (166,292)	$ -
Initial recognition of operating lease right to used liabilities	$ 166,292	$ -

See notes to Consolidated Financial Statements

NOTE A — ORGANIZATION AND BUSINESS

All references in this report to "Milestone Scientific," "us," "our," "we," the "Company" or "Milestone" refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Systems, Inc., Milestone Medical, Inc. and Milestone Education LLC (all described below), unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: C*ompuDent®; CompuMed®; CompuFlo®; DPS Dynamic Pressure Sensing technology®; Milestone Scientific ®; the Milestone logo ®; SafetyWand®; STA Single Tooth Anesthesia System®; and The Wand ®.*

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery device, using *The Wand®*, a single use disposable handpiece. The device is marketed in dentistry under the trademark*CompuDent®,* and *STA Single Tooth Anesthesia System®* and in medicine under the trademark *CompuMed®. CompuDent®* is suitable for all dental procedures that require local anesthetic.*CompuMed®* is suitable for many medical procedures regularly performed in Plastic Surgery, Hair Restoration Surgery, Podiatry, Colorectal Surgery, Dermatology, Orthopedics and many other disciplines. The dental devices are sold in the United States, Canada and in 60 other countries. To date there have been five (5) medical devices sold in the United States and limited amounts sold internationally, although certain medical devices have obtained CE mark approval and can be marketed and sold in most European countries. In June 2017, Milestone Scientific received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the *CompuFlo®* Epidural Computer Controlled Anesthesia System ("Epidural").

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra- articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA Office of Device Evaluation, we intended to file a new 510(k) application for the device in 2019, however, due to financing constraints, a new 510(k) application was not filed in 2019. The Company plans to file a new 510(k) application for the device in 2020, subject to sufficient funds being available.

In November 2018, Milestone Scientific received a letter from NYSE American LLC (the "Exchange") stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the "Company Guide").On December 20, 2018, the Company submitted a plan of compliance (the "Plan") to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020. On January 24, 2019, the Company received a letter from the Exchange stating that the Company's Plan has been accepted. The Company is not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide.

In February 2019, Milestone Scientific consummated a public offering and a private placement of common stock. The public offering generated gross proceeds of approximately $2.0 million for the issuance of 5,715,000 shares of common stock and warrants to purchase 1,428,750 shares of common stock. The warrants terms are 5 years and they are exercisable at $0.50 per share. Subsequent to the public offering the underwriter exercised its over-allotment option and paid approximately $198,000 for 567,400 additional shares of common stock and as well as 141,850 warrants.

Also, in February 2019, the Company generated gross proceeds from a private placement of approximately $250,000 for 714,286 shares of common stock and warrants to purchase 178,571 shares of common stock from Bp4 S.p.A., a principal stockholder of Milestone Scientific, that exercised its right to participate on a pro-rata basis on the aforementioned public offering. Bp4's CEO is a director of Milestone Scientific and also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific. The warrants terms are 5 years and they are exercisable at $0.50 per share.

NOTE B- GOING CONCERN AND LIQUIDITY

The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception. At December 31, 2019, the Company's cash on hand of $1.5 million. Based on the expected cash needed for operating activities, the Company's current cash and liquidity is not sufficient to finance the operating requirements for at least the next 12 months from the filing date of this annual report. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, the reduction in operating expenses and other strategic plans or transactions. As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of Covid-19, we anticipate that our revenue for the second quarter, and possibly the third quarter, will be materially and adversely affected. At this point in time, it is too early to determine an estimate of what the second or third quarter impact will be or the effect Covid-19 may have on our fourth quarter revenue. In addition, it is too early to determine what the effect will be on the anticipated commercialization of our CompuFlow Epidural system as a medical device in 2020. See Note R- *Subsequent Events.* Management is actively pursuing financing and/or other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all. Further, as a result of the extreme volatility in the financial markets due to the continuing spread of Covid-19, we may not be able to raise capital when needed or in sufficient amounts or execute other strategic plans or transactions.

These consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recover ability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern.

NOTE C — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1. Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of Milestone Scientific and its wholly owned and majority owned subsidiaries, including, Wand Dental (wholly owned), Milestone Advanced Cosmetic (majority owned) and Milestone Medical (majority owned). Milestone Education was a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. During 2018, Milestone Scientific purchased the remaining 50% increasing its ownership of Milestone Education to 100%. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

2. Reclassifications

Certain reclassifications have been made to the 2018 financial statements to conform to the condensed consolidated 2019 financial statement presentation. These reclassification had no effect on net loss or cash flows as previously reported.

3. Use of Estimates

+

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the allowance for doubtful accounts, inventory valuation, and cash flow assumptions regarding evaluations for impairment of long-lived assets and going concern considerations, and valuation allowances on deferred tax assets. Actual results could differ from those estimates**.**

4. Revenue Recognition

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps:

i. identification of the promised goods or services in the contract;
ii. determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
iii. measurement of the transaction price, including the constraint on variable consideration;
iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606.

The Company derives its revenues from the sale of its products, primarily dental instruments, handpieces, and other related products. The Company sells its products through a global distribution network and that includes both exclusive and non-exclusive distribution agreements with related and third parties.

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Sales Returns

The Company records allowances for product returns as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights and the Company's historical experience with returns and the amount of product in the distribution channel not consumed by end users and subject to return. The Company relies on historical return rates to estimate returns. In the future, if any of these factors and/or the history of product returns change, adjustments to the allowance for product returns may be required.

Financing and Payment

Our payment terms differ by geography and customer, but payment is generally required within 90 days from the date of shipment or delivery.

Disaggregation of Revenue

We operate in two operating segments: dental and medical. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. See Note M for revenues by geographical market, based on the customer's location, and product category for the years December 31, 2019 and 2018.

5. Variable Interest Entities

A variable interest entity ("VIE") is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support or (ii) has equity investors who lack the characteristics of a controlling financial interest. A VIE is consolidated by its primary beneficiary. The primary beneficiary has both the power to direct the activities that most significantly impact the entity's economic performance and the obligation to absorb losses or the right to receive benefits from the entity that could potentially be significant to the VIE.

If Milestone Scientific determines that it has operating power and the obligation to absorb losses or receive benefits, Milestone Scientific consolidates the VIE as the primary beneficiary. Milestone Scientific's involvement constitutes power that is most significant to the entity when it has unconstrained decision-making ability over key operational functions within the entity.

Because Milestone Scientific has a variable interest in Milestone China, it considered the guidance in ASC 810, "Consolidation" as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

- Power Criterion: The power to direct the activities that most significantly impact the entity's economic performance; and
- Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE

Milestone Scientific does not have the ability to control the activities that most significantly impact Milestone China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of Milestone China to the CEO and a group of significant shareholders, including the CEO, of Milestone China who have the power to direct the activities that most significantly impact the economic performance of Milestone China. Management has concluded that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and is accounted for under the equity method. See Note H.

6. Cash and Cash Equivalents

Milestone Scientific considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At times, such investments, may be more than the Federal Deposit Insurance Corporation insurance limit.

7. Accounts Receivable

Milestone Scientific sells a significant amount of its product on credit terms to its major distributors. Milestone Scientific estimates losses from the ability or inability of its customers to make payments on amounts billed. Most credit sales are due within 90 days from invoicing. There have not been any significant credit losses incurred to date. As of December 31, 2019 and 2018, accounts receivable (non- related party) was recorded, net of allowance for doubtful accounts of $10,000.

8. Inventories

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or net realizable value. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess, slow moving, defective, and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirements. As of December 31, 2019 and 2018, inventory was recorded net of a valuation allowance for slow moving and defective inventory of approximately $768,000 and $763,000, respectively.

9. Equity Method Investments

Investments in which Milestone Scientific can exercise significant influence, but do not control, are accounted for under the equity method of accounting and are included in the long-term assets on the Consolidated Balance Sheets. Under this method of accounting, Milestone Scientific's share of the net earnings or losses of the investee is presented below the income tax line on the Consolidated Statements of Operations. Milestone Scientific evaluates its equity method investments whenever events or changes in circumstance indicate that the carrying amounts of such investments may be impaired. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period.

10. Furniture, Fixture and Equipment

Equipment is recorded at cost, less accumulated depreciation. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, which range from two to seven years. The costs of maintenance and repairs are charged to operations as incurred.

11. Intangible Assets – Patents and Developed Technology

Patents are recorded at cost to prepare and file the applicable documents with the US Patent Office, or internationally with the applicable governmental office in the respective country. The costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. Patents and other developed technology acquired from another business entity will be amortized at the estimated useful life of the patent. These patents and developed technology are recorded at the acquisition cost. Patent defense costs, to the extent applicable, are expensed as incurred.

12. Impairment of Long-Lived Assets

Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company's impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

- significant under performance relative to expected historical or projected future operating results,
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business
- significant negative industry or economic trends
- significant technological changes, which would render the technology obsolete

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs. See Note J.

13. Research and Development

Research and development costs, which consist principally of new product development costs payable to third parties, are expensed as incurred. Advance payments for the research are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

14. Income Taxes

Milestone Scientific accounts for income taxes pursuant to the asset and liability method which requires deferred income tax assets and liabilities to be computed for temporary differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

At December 31, 2019 and 2018, we had no uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Consolidated Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2016, 2017, and 2018 years are subject to audit by federal and state jurisdictions.

15. Basic and diluted net loss per common share

Basic earnings (loss) per common share is computed by dividing the net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. In periods where there is net income, we apply the two-class method to calculate basic and diluted net income (loss) per share of common stock, as our Series A Convertible Preferred Stock is a participating security. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. In periods where there is a net loss, the two-class method of computing earnings per share does not apply as our Series A Convertible Preferred Stock does not contractually participate in our losses.

The Company did not include any portion of outstanding options, warrants or convertible preferred stock in the calculation of diluted loss per common share because all such securities are anti-dilutive for all periods presented.

Since Milestone Scientific had net losses for 2019 and 2018, the assumed effects of the exercise of potentially dilutive outstanding stock options, warrants and convertible preferred stock were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options, warrants, and convertible preferred stock totaled 2,336,611 and 9,279,234 at December 31, 2019 and 2018, respectively.

16. Fair Value of Financial Instruments

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). We are required to classify fair value measurements in one of the following categories:

- Level 1 inputs which are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.
- Level 2 inputs which are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.
- Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of an input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels. As of December 31, 2019 and 2018 the Company does not have any assets or liabilities that were measured at fair value on a recurring basis.

During the year ended December 31, 2019 the Company did not have sufficient authorized shares to support the exercise of outstanding securities, and reclassified all outstanding warrants and certain employee stock options to liability classification, measured using level 3 inputs and reclassified all shares-to-be-issued measured using level 1 inputs, the trading price of the Company's stock. At December 17, 2019 the Company increased the number of authorized shares available, extinguishing the derivative liability. The roll forward of the liability associated with certain outstanding warrants an stock options which use level 3 inputs is as follows. Refer to Note K for more detail.

	December 31, 2019
Balance at beginning of year	$ -
Warrants issued in connection with public offering (See Note I)	376,497
Employee options reclassified as derivative liability	422,484
Change in value of derivative securities – exercised	500,000
Reversal of derivative liability for exercised warrants	(655,000)
Change in fair value of derivative securities - not exercised	820,954
Reversal of Level 3 of derivative liability to equity upon authorized share increase	(1,464,935)
Balance at end of period	$ -

17. Derivative Liability

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks; however, the Company has certain financial instruments that qualify as derivatives and are classified as liabilities on the balance sheet. The Company evaluates all its financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, "Derivatives and Hedging". Derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires a derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date. See Note K, Outstanding Equity Instruments in Excess of Authorized Shares.

18. Stock-Based Compensation

Milestone Scientific accounts for stock-based compensation under ASC Topic 718, Share-Based Payment. ASC Topic 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the Statements of Operations over the service period, as an operating expense, based on the grant-date fair values.

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model. See Note L.

19. Recent Accounting Pronouncements

In June 2016, the FASB issued a new standard ASU No.2016-13, "Financial Instruments – Credit Losses" (Topic 326). The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2022.

In November 2016, the FASB issued a new standard ASU No.2016-18, "Statement of Cash Flows – Restricted Cash" (Topic 230). The new standard provides guidance as to address the diversity of treatment of restricted cash on the statement of cash flows. The adoption of this standard did not have a material effect on its presentation within the statement of cash flows.

On November 28, 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, Fair Value Measurement: Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820), which changes the fair value measurement disclosure requirements of ASC 820. This ASU removes certain disclosure requirements regarding the amounts and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy and the policy for timing of transfers between the levels. This ASU also adds disclosure requirements regarding unrealized gains and losses included in Other Comprehensive Income for recurring Level 3 fair value measurements and the range and weighted average of unobservable inputs used in Level 3 fair value measurements. ASU 2018-13 is effective for all entities with fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of ASU 2018-13. The Company intends to adopt this standard in 2020 and does not expect a significant impact from its adoption.

On January 1, 2019, we adopted Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), by ASU 2018-11, which supersedes the lease accounting guidance under Topic 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance, which does not require the reassessment of the following: i) whether existing or expired arrangements are or contain a lease, ii) the lease classification of existing or expired leases, and iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. As of the adoption date, the Company identified three operating lease arrangements in which it is a lessee. The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $166,292 in the Company's condensed consolidated balance sheets. The adoption of the standard did not have a material effect on the Company's statements of operations or statements of cash flows. For information regarding the impact of Topic 842 adoption, see Note P – Commitments.

NOTE D — INVENTORIES

Inventories consist of the following:	December 31, 2019	December 31, 2018
Dental finished goods, net	$ 1,306,763	$ 1,609,000
Medical finished goods, net	213,861	188,133
Component parts and other materials	99,885	123,918
Total inventories	$ 1,620,509	$ 1,921,051

At December 31, 2019, there is a reserve for slow moving medical finished goods of approximately $450,000 and damaged slow moving dental finished goods of $318,000. In July 2019, United System issued a credit to the Company for approximately $151,000 for handpieces found to be defective. The Company recorded the credit in cost of sales because the Company previously recorded an allowance against the associated inventory during 2018. At December 31, 2018, there was a reserve for slow moving medical finished goods of $454,183 and damaged slow moving dental finished goods of $309,196. The reserve for the medical finished goods was provided due to the delay in commercialization of the intra-articular medical instrument.

NOTE E — ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA, and epidural inventory purchases and epidural replacements parts. The balance of the advances as of December 31, 2019 and 2018 is approximately $710,000 and $649,000 respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE F – INVESTMENT IN AND TRANSACTIONS WITH UNCONSOLIDATED SUBSIDIARIES

Milestone China Ltd.

Ownership

In June 2014, Milestone Scientific invested $1 million in Milestone China Ltd. ("Milestone China") by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting.

Related Party Transactions

Milestone China is Milestone Scientific's exclusive distributor in China. During 2017 and prior to the payment default during 2018, Milestone Scientific agreed to sell inventory to Milestone China and its agent. During 2018 Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and it's agents which amounted to $2.8 million at the time of the payment arrangement. The payment terms required payments of $200,000 per month beginning in July 2018 through November 2018 and a balloon payment of approximately $1,425,000 during December 2018. Milestone Scientific collected $950,000 under the payment arrangement which resulted in a deferred revenue and deferred cost balance of $1.8 million and $1.25 million, respectively, prior to Milestone China's default of the payment arrangement. Milestone China failed to make all the payments under the arrangement and due to the default on the arrangement and Milestone China's liquidity constraints, Milestone Scientific halted shipments to Milestone China and the Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a reserve against the related deferred cost of $1.25 million during the fourth quarter of 2018.

During the year ended December 31, 2019, Milestone Scientific recognized gross revenue associated with 2018 delivered products to Milestone China and its agents of approximately $259,000, offset by accepted returns of approximately $104,000. During 2018, Milestone Scientific recognized $900,000 of related party sales of handpieces and instruments to Milestone China and its agent.

As of December 31, 2018, Milestone Scientific had recorded deferred revenues and deferred costs associated with sales to Milestone China and it's agents of $100,000 and $50,000, respectively. After 2019 collections, no deferred costs or deferred revenue remained as of December 31, 2019.

Gross Profit Deferral

Due to timing differences of when the inventory sold to Milestone China is recognized and when Milestone China sells the acquired inventory to third parties, an elimination of the profit is required as of the balance sheet date. In accordance with ASC 323 Equity Method and Joint Ventures, Milestone Scientific has deferred 40% of the gross profit associated with recognized revenue from sales to Milestone China until that product is sold to third parties.

At December 31, 2019 and 2018, the deferred profit was $340,476 and $421,800 respectively, which is included in deferred profit, related party in the consolidated balance sheets. For twelve months ended December 31, 2019 and 2018, Milestone Scientific recorded earnings on equity investment of $81,324 and $329,700 respectively, for product sold by Milestone China to third parties.

Equity Method Disclosures

As of December 31, 2019, and, 2018, Milestone Scientific's investment in Milestone China was $0. As of December 31, 2019, and 2018, Milestone Scientific's share of cumulative losses of Milestone China were $4,308,596 and $3,380,388, respectively, which have been suspended.

The following table includes summarized financial information (unaudited) of Milestone China:

Assets:	December 31, 2019 (unaudited)	December 31, 2018 (unaudited)
Current assets	$ 8,392,858	$ 10,587,648
Non-current assets	5,082,313	4,603,845
Total assets:	$ 13,475,171	$ 15,191,493
Liabilities and stockholders' deficit:		
Current liabilities	$ 17,910,452	$ 17,696,393
Stockholders' deficit	(4,435,281)	(2,504,900)
Total liabilities and stockholders' deficit	$ 13,475,171	$ 15,191,493

	December 31, 2019 (unaudited)	December 31, 2018 (unaudited)
Net sales	$ 3,401,025	$ 1,710,473
Cost of goods sold	1,724,882	789,957
Gross profit	1,676,143	920,516
Other expenses	(3,996,663)	(1,371,085)
Net loss	$ (2,320,520)	$ (450,569)

NOTE G— FURNITURE, FIXTURES AND EQUIPMENT

	2019	2018
Furniture, Fixtures and Equipment consist of the following:		
Leasehold improvements	$ 24,734	$ 24,734
Office furniture and equipment	134,947	134,947
Molds	7,200	7,200
Trade show displays	151,462	143,357
Computers and software	280,577	278,766
Tooling Safety Wand	125,022	125,022
Tooling equipment-STA & Wand	11,100	11,100
EPI and IA Instruments	82,363	82,363
STA Trials Instruments	63,752	63,752
Total	881,157	871,241
Less accumulated depreciation	(836,181)	(788,684)
Total	$ 44,976	$ 82,557

Depreciation expense was approximately $47,500 and $66,600 for the years ended December 31, 2019 and 2018, respectively.

NOTE H — PATENTS

	December 31, 2019			
	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	$ 1,377,863	$ -	$ (995,603)	$ 382,260
Total	$ 1,377,863	$ -	$ (995,603)	$ 382,260

	December 31, 2018			
	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	$ 1,377,863	$ -	$ (942,590)	$ 435,273
Epidural-Apad acquired patents	2,639,647	(1,539,794)	(1,099,853)	-
Total	$ 4,017,510	$ (1,539,794)	$ (2,042,443)	$ 435,273

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was $53,013 and $814,681 for the year ended December 31, 2019 and 2018, respectively. The annual amortization expense expected to be recorded for existing intangibles assets for the years 2020 through 2024 is approximately $53,000, $53,000, $53,000, $47,000 and $33,000.

On July 13, 2017, Milestone Scientific consummated an Asset Purchase Agreement (the "Agreement") with APAD Octrooi B.V. and APAD B.V. (each, a "Seller" and collectively, the "Sellers") pursuant to which Milestone Scientific acquired certain patent rights and other intellectual property rights related to the Sellers' computer-controlled injection instrument (the "Purchased Assets") accounted for as an asset acquisition. The patents purchased in the amount of approximately $2,639,000 were capitalized and were expected to be amortized over their three-year estimated useful life.

During 2018, the Company determined that the APAD Patents will not be further developed or commercialized before their estimated useful life expires. As such, Management determined that these assets were impaired and a charge of approximately $1.5 million was recorded.

NOTE I — STOCKHOLDERS' EQUITY

PUBLIC OFFERING AND PRIVATE PLACEMENT

In February 2019, Milestone Scientific consummated a public offering and a private placement of Common Stock. The public offering generated gross proceeds of approximately $2.0 million for the issuance of 5,715,000 shares of common stock and warrants to purchase 1,428,750 shares of common stock. The warrants' term is 5 years and they are exercisable at $0.50 per share. Subsequent to the public offering the underwriter exercised its over-allotment option and paid approximately $198,000 for 567,400 additional shares of common stock and 141,850 warrants.

Also, in February 2019, the Company generated gross proceeds from a private placement of approximately $250,000 for 714,286 shares of common stock and warrants to purchase 178,571 shares of common stock from Bp4 S.p.A., a principal stockholder of Milestone Scientific, that exercised its right to participate on a pro-rata basis on the recent public offering. Bp4's CEO is a director of Milestone Scientific and also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific. The warrants' terms are 5 years and they are exercisable at $0.50 per share.

WARRANTS

The following table summarizes information about shares issuable under warrants outstanding at December 31, 2019:

	Warrant shares outstanding	Weighted Average exercise price	Weighted Average remaining life	Intrinsic value
Outstanding at January 1, 2019	1,592,775	2.55	0.21	-
Issued	1,749,171	0.50	4.10	1,556,762
Exercised	(675,000)	0.50	-	532,413
Expired or cancelled	(1,592,775)	2.55	-	-
Outstanding and exercisable at December 31, 2019	1,074,171	0.50	4.10	956,012
Exercisable at December 31, 2019	1,074,171	0.50	4.10	956,012

PREFERRED STOCK

In May 2014, Milestone completed a private placement, which raised gross proceeds of $10 million, from the sale of $3 million of Milestone Scientific common stock (two million shares at $1.50 per share) and $7 million of our Series A Convertible Preferred Stock ("preferred stock") (7,000 shares at $1,000 per share). These shares were convertible, at the option of the holder, into the number of shares of common stock equal to the stated value divided by $2.545, subject to anti-dilution adjustments, at any time before May 14, 2019.

These shares were mandatory convertible on May 14, 2019, into the number of shares of common stock equal to the stated value divided by $2.54 per share or $1.50 per share if the common stock does not trade at $3.15 for period of time, as defined by the agreements, both subject to anti-dilution adjustment.

On May 14, 2019, the mandatory conversion date, the Preferred Stock was converted at a rate of $1.17 per common share resulting in the issuance of 5,982,906 shares of common stock.

SHARES TO BE ISSUED

As of December 31, 2019, there were 2,226,473 shares to be issued whose issuance has been deferred under the terms of an employment agreements with the Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. As of December 31, 2018, there were 1,908,814 shares, whose issuance has been deferred under the terms of an employment agreements with the Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. Such shares will be issued to each party upon termination of their employment.

As of December 31, 2019 and 2018, there were 149,287 and 561,752 shares to be issued to non-employees, respectively, that will be issued to non-employees for services rendered. The number of shares was fixed at the date of grant and were fully vested upon grant date.

The following table summarizes information about shares to be issue at December 31, 2019.

	December 31, 2019
Shares-to-be-issued, outstanding December 31, 2018	2,470,566
Granted in current year	2,103,793
Issued in current year	(2,198,599)
Shares-to-be-issued outstanding, December 31, 2019	2,375,760

OUTSTANDING EQUITY INSTRUMENTS IN EXCESS OF AUTHORIZED SHARES

As a result of the shares and warrants issued in the public and private offerings as well as other issuance of common stock during 2019, the Company did not have a sufficient number of authorized shares of common stock to cover the exercise and issue of outstanding equity instruments. Therefore, certain equity instruments are classified as liabilities until there is a sufficient number of authorized shares of common stock to cover the shares issuable upon exercise of the equity instruments. As long as these equity instruments are liability-classified, they will continue to be re-measured each reporting period, with any increase or decrease in value recorded as a loss or gain in the consolidated statement of operations.

During 2019, the Company initially reclassified approximately 1.6 million warrants issued during the 2016 capital raise, 1.7 million warrants during the 2019 capital raise, 0.6 million employee options, and 3.4 million shares to be issued, totaling approximately $-, $376,000, $422,000, and $1,405,000, respectively. During the year, approximately 665,000 of the warrants issued in 2019, and 1.3 million shares to be issued were exercised and issued, respectively. Through the exercise date and issuance date, these warrants and shares to be issued were marked to market and a loss of $0.5 million and $0.5 million was recognized, respectively. At the exercise and issuance dates, this resulted in a reclassification of the derivative liabilities to additional paid in capital of approximately $0.65 million and $1.07 million, respectively.

The fair value of the Company's shares to be issued is measured using the trading price of the Company's stock on the measurement and reclassification dates and the fair value of the warrants and stock options is determined using a Black-Scholes option pricing model on the measurement and reclassification dates

On December 17, 2019, the Company's shareholders increased the authorized share limit to 75,000,000, and the Company had sufficient authorized shares to cover the exercise and issuance of all outstanding securities, settling and reclassifying the outstanding derivative liability. At time of reclassification approximately 1.6 million warrants issued during 2016 capital raise, 1.1 million warrants during the 2019 capital raise, 0.6 million employee options, and 2.1 million shares to be issued, were marked to market for reported losses (gains) totaling approximately $-, $860,000, ($40,000), and $1,800,000, respectively or approximately $2.6 million. At December 17, 2019, the reclassification of derivative liabilities to additional paid in capital was approximately $-, $1,095,000, $380,000, and $2,640,000, respectively for a total of approximately $4.1 million.

The following assumptions were used to value the warrants and stock options at the reclassification to liability date:

	2016 Warrants	2019 Warrants	Employee Stock Options
Fair Value of Common Stock	$0.36-$.83	$ 0.33	$ 1.07 – 1.60
Expected Term	.2-.5 years	4.9 years	1.1 – 2.22 years
Volatility	86%-100%	83%	91.8 – 102.3 %
Dividend yield	0.00%	0.00%	0.00 %
Exercise Price	$ 2.55	$ 0.50	$ 1.04 – 2.09
Risk-free interest rate	1.88%-2.09%	2.30%	1.68 – 1.53 %
Weighted average fair value of securities granted	$ -	$ 0.22	$ 0.72
Number of shares underlying securities granted	1,592,775	1,749,171	592,358

The reclassification to derivative liability for the 2016 warrants, 2019 warrants, and employee stock options was approximately $ 0, $376,00 and $422,000, respectively. The 3.4 million shares to be issued were reclassified to derivative liability at the average common stock trading price of $0.42 in the amount of approximately $1.4 million.

During the year ended December 31, 2019 approximately 675,000 liability classified warrants were exercised. At time of exercise, these warrants were revalued using the following assumptions:

	2019 Warrants
Fair Value of Common Stock	$ 0.83 – 1.42
Expected Term	4.2 -4.3 years
Volatility	86 - 87%
Dividend yield	0.00%
Exercise Price	$ 0.50
Risk-free interest rate	1.38 – 1.73%
Weighted average fair value of warrants exercised	$ 0.98
Number of shares underlying warrants exercised	665,000

The reclassification to additional paid in capital was approximately $655,000, and a mark to market loss of approximately $500,000 was recognized up to the date of reclassification. In addition, during 2019, approximately 1.3 million shares to be issued were issued at a weighted average trading price $0.84 which resulted to a reclassification to additional paid in capital of $1.07 million and a mark to market loss of approximately $500,000 up to the date of reclassification.

In December 2019, upon the increase of the authorized shares of common stock to 75,000,000, the derivative liabilities associated with the lack of authorized shares were reclassified into equity and revalued using the following assumptions:

	2016 Warrants	2019 Warrants	Employee Stock Options
Fair Value of Common Stock	$ 1.28	$ 1.28	$ 1.28
Expected Term	0.1 years	4.1 years	1- 2.1 years
Volatility	38%	88%	92-102%
Dividend yield	0.00%	0.00%	0.00%
Exercise Price	$ 2.55	$ 0.50	$ 1.04 – 2.09
Risk-free interest rate	1.56%	1.71%	1.53 – 1.63%
Weighted average fair value of warrants granted	$ -	$ 1.01	$ 0.64
Number of shares underlying warrants granted	1,592,775	1,084,171	592,358

The reclassification to additional paid in capital for the 2016 warrants, 2019 warrants, and employee stock options was approximately $-, $1,095,000, $380,000, respectively. A mark to market loss (gain) of approximately $-, $860,000, and ($40,000) was recognized. In addition, the remaining 2.1 million shares to be issued resulted in a reclassification to additional paid in capital of approximately $2.7 million and a loss on re-measurement up to that date of approximately $1.8 million.

NOTE J — STOCK OPTION PLANS

The 2004 Stock Option Plan provided for the grant of options to purchase up to 750,000 shares of Milestone Scientific's common stock. Options may be granted to employees, officers, directors and consultants of Milestone Scientific for the purchase of common stock at a price not less than the fair market value of the common stock on the date of the grant. Generally, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. There were no shares available for grant at December 31, 2019 or 2018 under this plan.

In June 2011, the stockholders of Milestone Scientific approved the 2011 Stock Option Plan (the "2011 Plan") which originally provided for stock options to our employees, directors and consultants and incentive and non-qualified stock options to purchase up to 2,000,000 shares of common stock and was later amended in 2016 to increase the maximum number of shares reserved for grant to 4,000,000. Generally, options become exercisable over a three-year period from the grant date and expire five years after the date of grant.

Milestone Scientific recognizes compensation expense over the requisite service period and in the case of performance-based options over the period of the expected performance. For the twelve months ended December 31, 2019 and 2018, Milestone Scientific recognized $181,448 and $398,301 of total employee compensation cost, respectively. As of December 31, 2019 and 2018, there was $82,526 and $263,974 of total unrecognized compensation cost related to non- vested options, respectively. Milestone Scientific expects to recognize these costs over a weighted average period of 1 year and 1.75 years as of December 31, 2019 and 2018, respectively.

A summary of option activity for employees under the plans and changes during the years ended December 31, 2019 and 2018 is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Options outstanding December 31, 2017	1,985,335	1.74	3.04	25,160
Granted	-	-	-	-
Exercised during 2018	-	-	-	-
Forfeited or expired	(315,114)	1.50	-	-
Options outstanding December 31, 2018	1,670,221	1.71	2.40	-
Exercisable, December 31, 2018	1,317,632	1.79	2.15	-
Granted	-	-	-	-
Exercised during 2019	-	-	-	-
Forfeited or expired	(457,779)	1.96	-	-
Options outstanding December 31, 2019	1,212,442	1.61	2.00	114,570
Exercisable, December 31, 2019	1,117,834	1.65	1.90	88,982

A summary of option activity for non-employees under the plans and changes during the years ended December 31, 2019 and 2018, is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Options outstanding December 31, 2017	224,999	2.53	4.32	-
Granted	8,333	0.75	4.33	
Exercised during 2018	-	-	-	-
Forfeited or expired	(200,000)	2.55	-	
Options outstanding December 31, 2018	33,332	1.87	2.94	
Exercisable, December 31, 2018	27,777	2.10	2.66	
Granted	16,666	0.55	4.43	13,999
Exercised during 2019	-	-	-	-
Forfeited or expired	-	-	-	
Options outstanding December 31, 2019	49,998	1.43	2.94	19,333
Exercisable, December 31, 2019	36,109	1.76	2.44	8,222

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model at the date of grant. For the twelve months ended December 31, 2019 and 2018, Milestone Scientific recognized $2,439 and $9,384 expense related to non-employee options, respectively.

NOTE K–EMPLOYMENT CONTRACT AND CONSULTING AGREEMENTS

Employment Contracts

On December 1, 2016, Wand Dental and Gian Domenico Trombetta ("Trombetta") entered into an Amended and Restated Employment Agreement (the "Agreement"), pursuant to which Trombetta receives base compensation of $280,000 per year and is eligible to receive annual bonuses in the sole discretion of the Compensation Committee. Pursuant to the Agreement, Trombetta will continue to serve as the Chief Executive Officer of Wand Dental for a period of one-year beginning on September 1, 2016 through August 31, 2017 (the "Employment Term"). The Employment Term automatically renews for a one-year period, from September 1st through August 31st of each successive year (each a "Renewal Term"), unless prior to June 1st of the Employment Term or any Renewal Term, as applicable, either party notifies the other that he or it chooses not to extend the term of employment in accordance with the terms of the Agreement.

In July 2017, Milestone Scientific entered into a ten-year employment agreement with Leonard Osser, who previously served as the Company's President and Chief Executive Officer, to serve as Managing Director – China Operations. This agreement provides for annual compensation of $300,000 consisting of $100,000 in cash and $200,000 in the Company's common stock valued at the average closing price of the Company's common stock on the NYSE or such other market or exchange on which its shares are then traded during the first fifteen (15) trading days of the last full calendar month of each year during the term of this agreement. This agreement supersedes all prior employment agreements between Mr. Osser and Milestone Scientific. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term.

In July 2017, Mr. Osser also resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive $100,000 per year for Mr. Osser's services.

On December 19, 2017 the Board of Directors appointed Leonard Osser Interim Chief Executive Office, replacing Leslie Bernhard .Mr. Osser placed on hold his position as Managing Director-China Operations and his consulting agreement with Milestone Medical to rejoined Milestone Scientific Inc. as Interim Chief Executive Officer and will not receive or earn any compensation under those agreements until he is no longer Interim Chief Executive Officer. Mr. Osser as Interim Chief Executive Officer receives a base salary and may receive bonus determined by the compensation committee of Company.

NOTE L — INCOME TAXES

Due to Milestone Scientific's history of operating losses, a full valuation allowances have been provided for all of Milestone Scientific's deferred tax assets. At December 31, 2019 and 2018, no recognition was given to the utilization of the remaining net operating loss carry forwards in each of these periods.

Deferred tax attributes resulting from differences between financial accounting amounts and tax bases of assets and liabilities at December 31, 2019 and 2018 are as follows:

	2019	2018
Allowance for doubtful accounts	$ 2,000	$ 3,000
Warranty reserve	5,000	29,000
Impaired Assets	-	435,000
Inventory Reserve	178,000	551,000
Deferred officers' compensation	820,000	715,000
Depreciation and Amortization	(103,000)	345,000
Net operating loss carryforward	16,504,000	16,500,000
Tax Credit	384,000	-
Other	(28,000)	-
Subtotal	17,762,000	18,578,000
Valuation allowance	(17,762,000)	(18,578,000)
Non-current deferred tax asset	$ -	$ -

As of December 31, 2019, federal net operating loss carry-forwards are approximately $59,000,000. As of December 31, 2018, Milestone Scientific has federal net operating loss carry-forwards of approximately $65,300,000, which is comprised solely of losses attributable Milestone Scientific and its subsidiaries. Net operating losses generated before December 31, 2017 will be available to offset future income, if any, through December 2037. Net operating losses generated in 2018 or after can be carried forward indefinitely. As of December 31, 2019, state net operating losses were approximately 56,700,000.

As of December 31, 2019 and 2018, Milestone, Scientific has state net operating loss carry-forwards of approximately $39,400,000 and $30,800,000, respectively. Net operating losses will be available to offset future taxable income, if any, through December 2039.

The utilization of Milestone Scientific's net operating losses may be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carry forwards before their utilization. Milestone Scientific has established a 100% valuation allowance for all its deferred tax assets due to uncertainty as to their future realization.

As of December 31, 2019, and 2018, state tax liability was approximately $18,000 and $24,000 respectively. Such expense was recognized in the accompanying consolidated financial statements.

Accounting for uncertainties in income taxes prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition. At December 31, 2019 and 2018, we had no uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2016, 2017, and 2018 years are subject to audit by federal and state jurisdictions.

A reconciliation of the statutory tax rates for the years ended December 31, is as follows:

	2019	2018
Statutory rate	21%	21%
State income tax-all states	4%	7%
Change in fair value of derivative	-11%	0%
NOL Expiration	-22%	0%
Other	-3%	0%
Subtotal	-11%	28%
Valuation allowance	11%	-28%
Effective tax rate	0%	0%

NOTE M — SEGMENT AND GEOGRAPHIC DATA

We conduct our business through two reportable segments: dental and medical. These segments offer different products and services to different customer base. The following tables present information about our reportable and operating segments:

	Years Ended December 31,	
Sales		
Net Sales:	**2019**	**2018**
Dental	$ 8,336,901	$ 9,502,276
Medical	37,600	119,800
Total net sales	$ 8,374,501	$ 9,622,076

Operating Income (Loss):	**2019**	**2018**
Dental	$ 2,775,716	$ 1,373,178
Medical	(2,350,103)	(2,611,231)
Corporate	(4,424,606)	(6,761,282)
Total operating loss	$ (3,998,993)	$ (7,999,335)

Depreciation and Amortization:	**2019**	**2018**
Dental	$ 15,793	$ 16,474
Medical	8,392	24,492
Corporate	76,323	840,319
Total depreciation and amortization	$ 100,508	$ 881,285

Income (loss) before taxes and equity in earnings of affiliates:	**2019**	**2018**
Dental	$ 2,774,332	$ 1,363,662
Medical	(2,353,194)	(2,704,630)
Corporate	(8,064,576)	(6,658,152)
Total loss before taxes and equity in earnings of affiliate	$ (7,643,438)	$ (7,999,120)

Total Assets	2019	2018
Dental	$ 5,008,324	$ 5,169,944
Medical	590,727	328,208
Corporate	957,238	902,816
Total loss before taxes and equity in earnings of affiliate	$ 6,556,289	$ 6,400,968

The following table presents information about our operations by geographic area as December 31, 2019 and 2018. Net sales by geographic area are based on the respective locations of our subsidiaries

Total Product Sales-Dental	2019	2018
Domestic-US and Canada	$ 4,512,904	$ 4,798,706
International Rest of World	3,665,347	3,803,570
International-China	158,650	900,000
Total Product Sales-Dental	$ 8,336,901	$ 9,502,276
Total Product Sales-Medical		
Domestic-US and Canada	$ 13,700	$ 32,500
International Rest of World	23,900	87,300
International-China	-	-
Total Product Sales-Medical	$ 37,600	$ 119,800
Domestic-US and Canada	$ 4,526,604	$ 4,831,206
International Rest of World	3,689,247	3,890,870
International-China	158,650	900,000
Total	$ 8,374,501	$ 9,622,076

NOTE N-- CONCENTRATIONS

Milestone Scientific has informal arrangements with third-party US manufacturers of the STA, *CompuDent* and *CompuMed* devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current at December 31, 2019 and 2018. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations.

For the twelve months ended December 31,2019 an aggregate of approximately 53% of the Company's net product sales were from one US Distributor. For the twelve months ended December 31, 2018, an aggregate of approximately 53% of Wand Dental's net product sales were to two customers/distributors (one of which, Milestone China, is a related party), 43% and 10% respectively.

Accounts receivable for the major customer/distributors amounted to approximately or 77%, of Milestone Scientific's gross accounts receivable as of December 31, 2019. Accounts receivable for the major customer/distributors amounted to approximately or 82%, or 49% and 33% of Milestone Scientific's gross accounts receivable as of December 31, 2018. As of December 31, 2018, Milestone China owed $1,917,990 to Milestone Scientific. Due to the delinquent nature of the scheduled payments and Milestone China's further liquidity constraints, Milestone Scientific reduced accounts receivable, related party and deferred revenue, related party by $1,817,990 at December 31, 2018. Additionally, Milestone Scientific recorded a reserve of $1,250,928 against the associated deferred cost, related party.

Business interruptions, including any interruptions resulting from COVID-19,(see Note R-*Subsequent Events)* could significantly disrupt our operations and could have a material adverse impact on our business. All of our employees are located in the U.S. In addition to our employees, we rely on (i) distributors, agents and third-party logistics providers in connection with product sales and distribution and (ii) raw material and component suppliers in the U.S., Europe and China. If we, or any of these third party partners encounter any disruptions to our or their respective operations or facilities, or if we or any of these third party partners were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute, pandemic or other unforeseen disruption, then we or they may be prevented or delayed from effectively operating our or their business, respectively.

NOTE O -- RELATED PARTY TRANSACTIONS

United Systems

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal manufacturer of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were $1.2 million for the years ended December 31, 2019 and 2018. As December 31, 2019 and 2018, Milestone Scientific owed this manufacturer $943,000 and $1.3 million, respectively, which is included in accounts payable, related party on the consolidated balance sheets. In February 2019, Milestone Scientific board of directors granted United Systems 285,714 shares of stock at $0.35 or $100,000 for consulting services. These shares were issued July 2019.

During 2018 Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of December 31, 2019, Wand Dental has deferred royalty income of $342,540 that will be recognized at the earlier of when payment of the royalties is received from United Systems or when collectability is deemed to be assured and is included in accounts receivable, related party and deferred revenue, related party on the consolidated balance sheets. This receivable is included in the reserved receivables in Note F.

Also, during the year ended December 31, 2018, a Distribution Agreement between Wand Dental and United Systems was formed. Under the Distribution agreement United Systems purchased 1,000 STA instruments in June 2018, for delivery to Milestone China. Due to the related party nature and collectability concerns Wand Dental has deferred the sale. Milestone Scientific has deferred approximately $750,000 of related party sales of devices to Milestone China under the agreement with United Systems as of December 31, 2018. As of December 31, 2018, Milestone Scientific recorded accounts receivable, related party and deferred revenue, related party of $750,000 and deferred cost, related of $686,365, respectively. The deferred revenue, accounts receivable and deferred cost from this transaction are included in accounts receivable, deferred revenue and deferred cost related, party related to Milestone China disclosed on the consolidated balance sheets. This receivable, deferred revenue and deferred cost is included in the reserved receivables in Note F.

In July 2019, United System issued a credit to the Company for approximately $151,000 for handpieces founded to be defective. The Company recorded the credit in cost of sales since the Company previously recorded an allowance for against inventory during 2018.

Milestone China

Milestone Scientific owns a 40% interest in Milestone China. See Note F.

Other

As of December 31, 2019 and 2018 Milestone Scientific has deferred compensation and accrued pension due to Leonard Osser of approximately $493,000 and $386,000, respectively which is included accrued expenses related party.

As of December 31, 2019 and 2018 Milestone Scientific has deferred compensation due to Joseph D'Agostino of $56,800 and $28,400, respectively which is included accrued expenses related party.

As of December 31, 2019 and 2018 Milestone Scientific recorded deferred compensation for Gian Trombetta of approximately of and $380,000, and $216,000, respectively which is included accrued expenses related party.

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were $100,000 for years ended December 31, 2019 and 2018, respectively.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific, to provide consulting services. This agreement will renew for successive twelve-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were $80,000 for years ended December 31, 2019 and 2018, respectively.

The Director of Clinical Affairs' royalty fee was approximately $403,000 and $465,000 for the years ended December 31, 2019 and 2018, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $156,000 and $186,000 for the years ended December 31, 2019, and 2018, respectively. As of December 31, 2019 and 2018 Milestone Scientific owed the Director Clinical Affairs for royalties of approximately $390,000 and $364,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

NOTE P — COMMITMENTS

(1) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, CompuDent® and CompuMed® devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. In July 2019, the company entered into a new purchase commitment for the delivery of 1,400 STA CompuDent® instruments. As of December 31, 2019, the purchase order commitment was $1,067,073, and advances of $437,512 is reported in inventory advances.

In August 2019, the company entered a new purchase commitment for the delivery of 100 Epidural instruments beginning in 2020. As of December 31, 2019, we have an open purchase order of $299,000 for 100 Epidural instruments and have advanced $149,500 against this purchase commitment. The company also has advances on an open purchase order for long lead items for a future purchase order for the manufacturing of Epidural instrument in 2021, in which an advance of $123,649 is reported in inventory advances.

See Note R- *Subsequent Events*

(2) Leases

Operating Leases

In June 2015, the Company amended its original office lease of approximately 6,851 square feet for its headquarters in Livingston, New Jersey. Under the amendment, the Company leased an additional 774 square feet of rentable area of the building and extended the term of the lease through January 31, 2020 at a monthly cost of $12,522. The Company had an option to further extend the term of the lease, however, this option was not included in the determination of the lease's right-of-use asset or lease liability. Per the terms of the lease agreement, the Company does not have a residual value guarantee. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

In August 2019, the Company made the decision to not renew the existing office lease and instead signed a seven (7) year lease in a new facility (the "Roseland Facility"). The new facility is located in Roseland, New Jersey, the monthly lease payment is escalating, with a range of $9,275 - $10,898, and commences April 1, 2020.The Company is also responsible for electric charge equal to $2.00 per square foot which is equal to $11,130 annually, which shall be paid in equal monthly installments of $927.50. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company has utilized its incremental borrowing rate based on the long-term borrowing costs of comparable companies in the Medical Device industry.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined lease component, all contract consideration was allocated to the combined lease component.
- The expected lease terms include non-cancellable lease periods. Renewal option periods are not included in the determination of the lease terms as they were not reasonably certain to be exercised.

The components of lease expense as of December 31, 2019 were as follows:

Lease cost	As of December 31,2019
Operating lease expense	$ 158,218
Total lease expense	$ 158,218

Other information	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 158,218
Right-of-use assets obtained in exchange for new operating lease liabilities	-
Weighted-average remaining lease term - operating leases	0.2 years
Weighted-average discount rate - operating leases	9.20%

Maturity of lease liabilities	As of December 31, 2019
2020	16,030
2021	-
2022	-
2023	-
2024	-
Thereafter	-
Total lease payments	16,030
Less: interest	(53)
Present value of lease liabilities	15,977

Total lease payments presented in the table above excludes legally binding minimum lease payments for operating leases signed for a the Roseland Facility that will commence April 1, 2020. Milestone Scientific had not taken physical control of the Roseland Facility as of December 31, 2019 and as a result has not recorded lease liabilities or right of use assets for the Roseland Facility as of December 31, 2019.

(3) Other Commitments

The technology underlying the Safety Wand® and *CompuFlo*®, and an improvement to the controls for *CompuDent*® were developed by the Director of Clinical Affairs and assigned to Milestone Scientific. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs will receive additional payments of 2.5% of the total sales of products using certain of these technologies, and 5% of the total sales of products using certain other of the technologies until the expiration of the last patent covering these technologies. If products produced by third parties use any of these technologies (under license from us) then the Director of Clinical Affairs will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license.

The Director of Clinical Affairs' royalty fee was approximately $403,000 and $465,000 for the years ended December 31, 2019 and 2018, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $156,000 and $186,000 for the years ended December 31, 2019, and 2018, respectively. As of December 31, 2019 and 2018 Milestone Scientific owed the Director Clinical Affairs for royalties of approximately $390,000 and $364,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

NOTE Q — PENSION PLAN

Milestone Scientific has a Defined Contribution Plan that allows eligible employees to contribute part of their salary through payroll deductions. Milestone Scientific does not contribute to this plan, but does pay the administrative costs of the plan, which were not significant.

NOTE R — SUBSEQUENT EVENTS

Since the year ended December 31, 2019, the Company issued 460,725 shares of common stock for warrants exercised at $0.50 for proceeds of $230,363.

The coronavirus (COVID-19) that was reported to have surfaced in Wuhan, China in December 2019 and that has now spread to other countries throughout the world could adversely impact our operations or those of our third-party partners. Additionally, the continued spread of the virus could negatively impact the manufacture, supply, distribution and sale of our products and our financial results. The extent to which the coronavirus impacts our operations or those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Such developments could have a material adverse effect on our financial results and our ability to conduct business as expected.

EXHIBIT 21.1

Subsidiaries

Subsidiary	**Jurisdiction of Incorporation**
Wand Dental , Inc.	Delaware
Milestone Medical Inc.	Delaware
Milestone Advanced Cosmetic Systems Inc.	Delaware
Milestone Education LLC (inactive February 28,2019)	Nevada

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 No. 333-209466 and No. 333-231178, and Registration Statements on Form S-8 File No. 333-134245 and No. 333-40413 of Milestone Scientific Inc. of our report dated March 30, 2020, relating to our audit of the consolidated financial statements of Milestone Scientific Inc. as of December 31, 2019, which appear in this Form 10-K. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ Friedman LLP
East Hanover, New Jersey
March 30, 2020

Exhibit 31.1

Rule 13a-14(a)/15d-14(a) Certification

I, Leonard Osser, certify that:

1. I have reviewed this annual report on Form 10-K of Milestone Scientific Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

/s/ Leonard Osser
Leonard Osser
Interim Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

Rule 13a-14(a)/15d-14(a) Certification

I, Joseph D'Agostino, certify that:

1. I have reviewed this annual report on Form 10-K of Milestone Scientific Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b. Any fraud, whether material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

/s/ Joseph D'Agostino
Joseph D'Agostino
Chief Financial Officer and Chief Operating
Officer (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18
U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Milestone Scientific Inc. ("Milestone") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard Osser, Interim Chief Executive Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone.

Date March 30, 2019

/s/ Leonard Osser
Leonard Osser
Interim Chief Executive Officer
(Principal Executive Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
PURSUANT TO 18
U.S.C. SECTION
1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Milestone Scientific Inc. ("Milestone") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph D'Agostino, Chief Financial Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone.

Date March 30, 2020

/s/ Joseph D'Agostino
Joseph D'Agostino
Chief Operating Officer
Chief Financial Officer
(Principal Financial Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.